

**LIFE SCIENCES
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SCIENCE • TECHNOLOGY
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IP NEWS

USPTO Rolls Out Rulemaking Notices to Implement America Invents Act

The U.S. Patent and Trademark Office (USPTO) issued several notices in the January 5, 2012, *Federal Register*, concerning proposed rulemakings that would implement procedural changes required under the America Invents Act. Comments on each of these proposals are requested by March 5.

The **first proposal** would revise USPTO's rules of practice relating to miscellaneous post-patent provisions under the Act, which (i) expanded the scope of information "that any party may cite in a patent file, to include written statements made by a patent owner before a Federal court or the United States Patent and Trademark Office (Office) regarding the scope of any claim of the patent," and (ii) provided how such information may be considered on *ex parte* reexamination, *inter partes* review or post grant review.

The **second proposal** would change patent practice rules to adopt a pre-issuance mechanism "for third parties to contribute to the quality of issued patents by submitting to the Office, for consideration and inclusion in the record of patent applications, any patents, published patent applications, or other printed publications of potential relevance to the examination of the applications." The **third proposal** would implement the Act's statute of limitations for disciplinary proceedings brought against "any person, agent, or attorney who fails to comply with the regulations established under 35 U.S.C. 2(b)(2)(D)." The proposal would clarify when misconduct forming the basis for a disciplinary proceeding is made known to USPTO.

USPTO also issued a **notice** of proposed rulemaking on January 6 to "implement the inventor's oath or declaration provisions of the Leahy-Smith America Invents Act." Comments on this proposal are requested no later than March 6. The proposal would amend 37 C.F.R. parts 1 and 3.

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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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If you have questions about this issue of the Report, or would like to receive supporting documentation, please

NEW BIO BUSINESS VENTURES

Pharmaceutical Cos. Sign Agreement to Establish Joint Venture in China

Amerigen Pharmaceuticals and VIWA Pharmaceutical Co. have signed a memorandum of understanding (MOU) to establish a joint venture to develop, register and sell generic drugs in China. Once approved, the products would be manufactured at Amerigen's Chinese State Food and Drug Administration- and U.S. Food and Drug Administration-approved finished-dose plant in Suzhou, China.

"Combining Amerigen's development capabilities, manufacturing assets and access to products from Western markets with VIWA's access to APIs [active pharmaceutical ingredients] and regulatory expertise in China should enable the joint venture to rapidly build up its product portfolio," said VIWA's managing director Jack Ye. "This in turn will help accelerate VIWA's strategic thrust into the commercialization of finished pharmaceutical products in China." See *Amerigen Pharmaceuticals Press Release*, January 11, 2012.

INVESTOR NEWS

India's Biocon Founder Kiran Mazumdar-Shaw Profiled in *The New Yorker*

The New Yorker opened 2012 with a "Letter from Bangalore" article profiling India's wealthiest self-made woman, Kiran Mazumdar-Shaw, who founded the country's largest biotechnology company. Biocon, which went public in 2004 and employed more than 5,000 people a year later, develops pharmaceuticals of particular benefit to the nation's poorest citizens. Initially, the company produced enzymes, one of which was created for Ocean Spray, and now it focuses on biosimilars. Mazumdar-Shaw apparently faced obstacles as a professional woman and entrepreneur in India, but persevered to achieve the success that has allowed her to pursue philanthropic work, such as establishing a cancer center, clinics, health-monitoring network, and micro-insurance program, that is intended to provide a model to reform health care. See *The New Yorker*, January 2, 2012.

VC Firm to Invest \$200 Million in Life Sciences Companies

The venture capital (VC) firm Canaan Partners has announced the closing of its ninth fund with \$600 million available to invest in information technology and life sciences. According to General Partner John Balen, one-third of the capital will be set aside for companies developing pharmaceuticals, medical devices and diagnostics, and most of the investments will go to early- and

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seed-stage companies. In 2011, about one-quarter of Canaan's eighth fund was invested outside the United States, and Balen reportedly indicated that the same should be expected in 2012. The firm maintains offices in Israel and India, in addition to California, Connecticut and New York. *See CNN Money*, January 9, 2012; *MedCity News eNewsletter*, January 20, 2012.

CytoPherx Completes \$34-Million Funding Round for Kidney Inflammation Treatment

Ann Arbor, Michigan,-based CytoPherx, Inc. has secured \$34 million to complete U.S. clinical trials and gain Food and Drug Administration approval to market its anti-inflammatory therapy for acute kidney injury. Participants in the round include a large syndicate of investors co-led by Early Stage Partners, ONSET Ventures and Capital Midwest Fund.

CytoPherx's treatment focuses on acute systemic inflammation that is not well addressed with currently available therapies. "Mortality rates of patients experiencing acute kidney injury combined with multi-organ failure and/or severe sepsis and requiring Continuous Renal Replacement Therapy (CRRT) are often greater than 50 percent," CEO Jim Danehy said. "Our early trials have shown the potential of reducing this by as much as 15 percent." Approximately 160,000 people in the United States receive CRRT, he added, representing "a multi-billion dollar potential market opportunity for CytoPherx." *See Business Wire*, January 4, 2012.

Norwegian Biopharmaceutical Raises \$8.8 Million to Advance Kinase Inhibitor Drug

BerGenBio AS, based in Bergen, Norway, has completed an \$8.8-million Series A financing round targeted to take its lead cancer compound BGB324 into clinical trials and to develop a companion diagnostic. According to the company, lead investors were Sarsia Seed AS and Investinor AS.

"This significant new funding from both existing investors and now from Investinor, we believe supports our decision to focus on developing BGB324, our first-in-class Axl kinase inhibitor drug, rapidly towards clinical trials," said BerGenBio's CEO Richard Godfrey. According to data presented at the annual American Society for Hematology conference in San Diego, BGB324 inhibited tumor development in preclinical acute myelogenous leukemia models. The company also presented data showing that "inhibition of Axl blocks the epithelial-mesenchymal transition (EMT) in cancer cells and has the potential to delay or prevent metastasis, overcome and even reverse acquired resistance to chemotherapy and possibly prevent cancer recurrence," Godfrey said. *See BerGenBio Press Release*, January 4, 2012.

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MedGenesis Raises \$5 Million to Develop Treatment for Parkinson's Disease

MedGenesis Therapeutix Inc. has reportedly raised \$5 million to support Phase II clinical development of glial cell-derived neurotrophic factor protein (GDNF) in Parkinson's disease. According to the privately held biotechnology company, which is currently focused on developing treatments for neurologic diseases, GDNF "is a naturally-occurring growth factor capable of protecting and promoting the survival of dopamine producing nerve cells."

"This financing will assist us in the completion of the Phase II clinical program for GDNF and allows us to now shift our focus to financing our Phase III program, including the development of pharmaceutical company partnerships," CEO Erich Mohr said. "We are hopeful that this potentially disease-modifying treatment will significantly change the quality of life of patients with Parkinson's disease as well as have applications in other neurological indications." See *MedGenesis Therapeutix Press Release*, January 10, 2012.

Connecticut Medical-Device Startup Lands \$1.6 Million

EpiEP Inc., a Connecticut-based medical device company that launched with technology developed at the University of Virginia, has reportedly received \$1.6 million in a new funding round. According to the company's U.S. Securities and Exchange Commission filing, the startup raised the money through equity, debt and options or warrants for equity from nine unnamed investors. With total funding for the company currently at \$4.6 million, EpiEP's initial product, the EpiAccess system, was developed as a minimally invasive treatment to help control certain cardiac arrhythmias and other conditions. See *Mass High Tech*, January 6, 2012.

Daktari Diagnostics Secures \$10 Million to Advance Medical Testing Technology

Massachusetts-based Daktari Diagnostics Inc. has reportedly secured \$10 million in a staged financing round from a syndicate of private and venture investors, including Norwich Ventures and Partners Innovation Fund. According to Daktari, the financing "will be used to complete development and bring to market its initial products, intended for use in monitoring HIV patients worldwide, and to expand the point-of-care product development pipeline." Initially developed at Massachusetts General Hospital in Boston, the company's diagnostic system analyzes small volumes of blood or other fluids for use in health care settings. See *Daktari Diagnostics Press Release*, December 23, 2012.

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Massachusetts Startup Raises \$4 Million for Cellulosic Biofuel Development

Cambridge-based Novogy Inc. has reportedly raised \$4 million of a planned \$7.5-million funding round to develop cellulosic biofuels specifically made from waste paper sludge. According to the company's U.S. Securities and Exchange Commission filing, three unnamed investors participated in the funding round. See *Mass High Tech*, January 6, 2012.

BUSINESS CLIMATE

IPOs Sluggish in 2011 on Disappointing Returns

Biotech initial public offerings (IPOs) tracked the market as a whole in 2011, with fewer filed and returns in the negative column. According to market analysts, with the backlog of public offerings continuing to grow and national economies sluggish, 2012 may not offer any relief. Just 13 biotech firms went public in 2011, and of the 29 that launched since 2010, some two-thirds are now apparently trading at a loss to investors. Seventy percent of all companies that went public in 2011 are reportedly trading below their offering prices. Investors will likely continue to look for companies with products in later stages of development or demand a valuation discount from those startups that choose to go public. See *Genetic Engineering & Biotechnology News*, December 30, 2011; *The New York Times DealBook*, January 4, 2012.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Congress Continues to Address Reauthorization of FDA User Fee Law

With a number of hearings scheduled before House committees in February 2012, Congress is apparently on track to complete work on measures that would reauthorize the Food and Drug Administration (FDA) to collect user fees before the current law expires on September 30. The agency has apparently cleared three of four user-fee programs with stakeholders; they involve prescription, generic and biosimilar drugs. The medical-device user-fee program is still under discussion with FDA reporting 29 meetings with affected parties since January 2011. Senators Tom Harkin (D-Iowa) and Michael Enzi (R-Wyo.) reportedly said, "Moving forward, we expect the FDA and the medical device industry to continue to work together to resolve any outstanding issues quickly so our committee can move forward with the work to authorize all four user fee agreements in a timely manner."

According to a news source, FDA's prescription drug fee reauthorization proposal, which does not apparently face any congressional opposition, calls for a \$100 million increase in fees to cover the costs associated with 100 additional staff members, two additional sponsor meetings during the drug

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review process and a two-month extension of FDA's new-drug review process. The sticking point in the debate over medical-device fees is coming from the industry and patient advocates: manufacturers seek changes to the current expedited review process for low-risk devices, and advocacy organizations contend the existing system is too lax, allowing dangerous devices to enter the marketplace with cursory or no oversight. User fees reportedly comprise approximately one-third of FDA's budget. *See The Hill*, January 12, 2012; *CQ Today Online News*, January 13, 2012; *Reuters*, January 14, 2012.

FDA Issues Industry Guidance on Off-Label Information about Drugs, Medical Devices

The Food and Drug Administration (FDA) has issued [draft guidance](#) on how the pharmaceutical and medical device industry should respond to unsolicited requests for off-label information about their FDA-approved prescription drugs and medical devices. FDA [seeks](#) comments by March 29, 2012.

According to the draft, FDA would allow drug and device makers to provide information about off-label uses only for unsolicited requests that are not initiated by the drug or device maker or distributor. The guidance affirms FDA's view that companies can respond to unsolicited requests for FDA-regulated products in a "truthful, non-misleading, and accurate manner," even if the information relates to an unapproved or uncleared indication or condition of use, i.e., off-label uses or treatment regimens that the agency recognizes "may be important therapeutic options and may even constitute a medically recognized standard of care."

The guidelines define both nonpublic and public unsolicited requests. Nonpublic unsolicited requests are those "directed privately to a firm using a one-on-one communication approach." Public unsolicited requests "are made in a public forum, whether directed to a firm specifically or to a forum at large." According to FDA, the latter category has proliferated in recent years because "the rapid growth of the Internet, including social media tools and other emerging technologies, has made it easier for both consumers and health care professionals to quickly seek information about medical conditions and treatments. Many firms have also used emerging electronic media to disseminate product information. . . . through product websites, discussion boards, chat rooms, or other public electronic forums that they maintain and over which they have full control."

FDA made seven recommendations for responding to nonpublic unsolicited requests, including: (i) responses should be tailored to answer only the specific questions, (ii) information should be scientific in nature, and (iii) information should be generated by "medical or scientific personnel independent from sales or marketing departments." The agency made four recommendations for public unsolicited requests, including: (i) a firm should respond only

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when the request pertains specifically to its own named product and is not solely about a competitor's product, (ii) a firm's response "should be limited to providing [its] contact information and should **not** include any off-label information," and (iii) responses "should not be promotional in nature or tone."

In a related development, FDA has established a [docket](#) in response to a citizen petition to obtain comments and information on "scientific exchange about both unapproved new uses of products already legally marketed ('off-label' use) and use of products not yet legally marketed for any use."

The agency is particularly interested in (i) how FDA should define scientific exchange, (ii) the boundaries between scientific exchange and promotion, and (iii) whether investigational new drugs and investigational new devices should be treated the same way with respect to scientific exchange. The agency requests comments by March 27.

FDA Launches Blog to Provide Insights into Public Health Issues

The Food and Drug Administration (FDA) has launched a [blog](#) that, in the words of Commissioner Margaret Hamburg, will provide "insights on some of the most pressing public health issues of the day." Known as "FDA Voice," the blog will provide agency officials and employees the opportunity to write about the projects on which they are working and how those projects could affect the public. Early postings discuss FDA's efforts to address HIV/AIDS, agency priorities for 2012, guidance for parents administering acetaminophen to their children to ease cold and flu symptoms, and how the agency is making its medical device approval process more transparent.

California Initiates Voter Petition Seeking Mandatory Labeling on Biotech Foods

A group of environmentalists is reportedly seeking to qualify a voter initiative in California that would require special labels on foods containing genetically engineered (GE) ingredients. With 504,760 signatures needed by June 4, 2012, to be eligible for the November 6 ballot, the environmentalists claim that the Environmental Protection Agency and other agencies have not adequately regulated GE material.

"After 20 years of biotech bullying and force-feeding unlabeled and hazardous genetically modified foods to animals and humans—aided and abetted by the Clinton, Bush, and Obama administrations—a critical mass of food and health activists have decided it's time to move beyond small skirmishes and losing battles and go on the offensive," asserts Ronnie Cummins, national director of the Organic Consumers Association, which is one of the organizations supporting the petition. Cummins evidently hopes the initiative will mimic California's Proposition 65, a 1986 voter initiative that requires consumer warnings about exposures to chemicals known to the state to be

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carcinogens or reproductive toxicants.

According to California Secretary of State Debra Bowen, the proposed initiative would require labeling on “raw or processed food offered for sale to consumers if [the] food or any of its ingredients contain or are made from plants or animals with genetic material that has been changed in specified ways.” Exempted foods would be “certified organic; unintentionally produced with genetically engineered material; made from animals fed or injected with genetically engineered material but not genetically engineered themselves; processed with or containing only small amounts of genetically engineered ingredients; administered for treatment of medical conditions; sold for immediate consumption such as in a restaurant; or alcoholic beverages.” The initiative could cost state and local governments “several millions of dollars annually” to monitor and enforce its requirements. *See Cal. Secretary of State Press Release, January 5, 2012; Inside Cal/EPA, January 13, 2012.*

LITIGATION

[Lisa Larrimore Ouellette, “What Are the Sources of Patent Inflation? An Analysis of Federal Circuit Patentability Rulings,” *The Yale Law Journal Online*, January 2012](#)

Authored by a recent Yale Law School graduate who is currently clerking in the Federal Circuit Court of Appeals, this article challenges a model developed by Law Professor Jonathan Masur to explain why the boundaries of patentability have expanded since that court was created.

Larrimore Ouellette analyzes Federal Circuit patentability rulings from five different years and concludes that “reversals of [U.S. Patent and Trademark Office] rejections are few in number and doctrinally insignificant.” She finds instead that infringement-suit rulings on patentability “likely play an important role in patent inflation because of the presumption of patent validity and the higher stakes in patent litigation.” According to the author, “a complete model should acknowledge doctrinal presumptions, the different stakes for parties in different postures (and the varying amounts those parties are therefore willing to invest in litigation), as well as the important role of the [U.S.] Supreme Court in causing large shifts in the boundaries of patentability.”

NEWS BYTES

The Food and Drug Administration [requests](#) comments by April 26, 2012, on its “Draft Guidance for Industry and Food and Drug Administration Staff; The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)].”

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The Food and Drug Administration **seeks** comments by February 21, 2012, on issues relating to its authority “to require or order safety labeling changes for approved prescription drug products based on new safety information that becomes available after a drug product is approved.”

The U.S. Patent and Trademark Office **proposes** revising the patent term adjustment provisions relating to appellate review set forth in its rules of practice in patent cases. Comments are requested by January 27, 2012.

The U.S. Patent and Trademark Office (USPTO) issues a **notice** informing U.S. applicants who later file with the European Patent Office (EPO) that USPTO is providing search results electronically to its European counterpart so that U.S. applicants subject to the European Patent Convention “will not need to separately file their U.S. search results with the EPO, thereby providing time and costs savings to these applicants.”

UPCOMING CONFERENCES & SEMINARS

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Practice Partners **Scott Saylor** and **David Brooks** will participate in **DRI's Drug and Medical Device Seminar** slated for May 10-11, 2012, in New Orleans, Louisiana. Co-sponsored by SHB, the event will feature “trial skills demonstrations, panel discussions of judges overseeing coordinated pharmaceutical proceedings, and litigation insights from leading defenders of drug and device cases.” Brooks will present a session titled “When a Good Medical Device Fails: Successfully Defending Medical Device Suits When Causation Is Not in Doubt,” which will address the substantive and strategic consideration of defending these cases. Saylor will also deliver remarks as chair of DRI's Drug and Medical Device Committee.

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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.

