Shook, Hardy & Bacon L.L.P.

ISSUE 30 | MARCH 1, 2012

# LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS



## IP NEWS

### Fee Increases Top Discussion at First USPTO Public Meetings on AIA Implementation

The U.S. Patent and Trademark Office (USPTO) is conducting a series of public meetings around the country to familiarize practitioners with its proposals to implement patent reforms under the America Invents Act (AIA). According to news sources, the initial meetings have been dominated by concerns over fee increases, including an increase to $17,750 from $2,520 for an *ex parte* reexamination.

The patent community is also apparently concerned about the increase in fees based on the number of patent claims challenged. For example, some critics asserted that the cost of challenging 200 claims of a patent would be $590,000 for post-grant review or $450,000 for *inter partes* review. USPTO representatives cited significant backlogs (650,000 unexamined patent applications), as well as statistics showing that few reexaminations involve more than 70 contested claims, to defend the fee increases, noting that they will be used to hire and train new examiners.

USPTO Director David Kappos was quoted as saying, "From a principle perspective, it has been said many times, you get what you pay for and there is no such thing as a free lunch." Another matter raised during the meetings was why the proposed rules do not define what constitutes being "charged with infringement" in relation to eligibility for filing a petition challenging a covered business method patent. USPTO personnel responded by requesting public comments that propose a definition. Remaining public meetings will be held March 2, 2012, in Fort Lauderdale, Florida; March 5 at the Boston Public Library; and March 7 at the Chicago Public Library. *See Law 360*, February 23, 2012; *Bloomberg BNA Life Sciences Law & Industry Report*, February 24, 2012.

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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

## INVESTOR NEWS

### Colorado Life Sciences Industry Benefits from Increased VC Investments in 2011

A Boulder, Colorado-based company that tracks, analyzes and reports global bioscience venture capital investment activity has released a report on 2011 trends, finding an increase in funding and deals from 2010. In Colorado, for example, six biotech companies received venture capital funding in 2011, compared to four in 2010. And the amounts invested totaled $66.1 million in 2011, compared to $45.6 million in 2010. According to OnBioVC, which prepared the report, the telemedicine and medical device sectors saw the most activity.

### Seattle Biotechnology Company Secures $10 Million for *In Vitro* Molecular Diagnostics Development

Seattle-based Integrated Diagnostics (InDi®) has reportedly secured $10 million in its third and final tranche of a $30-million Series A venture financing started in 2009. Led by InterWest Partners and joined by The Wellcome Trust and the Grand Duchy of Luxembourg, the latest funds will be used to complete clinical development of the company's *in vitro* proteomic-based diagnostics programs and advance its novel class of molecules—protein-catalyzed capture agents.

InDi® said it plans to market its new "large-scale, blood-based molecular diagnostics that can detect important diseases like lung cancer and Alzheimer's at their earliest stages by simultaneously monitoring tens to hundreds of disease markers." InDi® CEO Albert Luderer told a news source that the company's goal was to produce the first commercial product within the next 13 months, with plans to eventually attempt an initial public offering if health-care insurers agree to pay for the new diagnostic tool. *See Integrated Diagnostics Press Release* and *Xconomy,* February 22, 2012.

### Seattle Biotech Files for $6 Million IPO for Breast Cancer Diagnostic Tests and Treatments

According to a U.S. Securities and Exchange Commission filing, Atossa Genetics reportedly plans to issue 1 million shares of stock in a $6-million initial public offering (IPO). Founded by Steven Quay in 2009, the Seattle, Washington-based biotech apparently plans to use the financing for production, sales and marketing of diagnostic tests for precursors to breast cancer.

Atossa's diagnostic tests include the mammary aspirate specimen cytology test (MASCT). Approved by the Food and Drug Administration to quickly and painlessly sample cells from nipple aspirate fluid, MASCT can evidently reveal changes in the breast years before current mammograms. Atossa's arsenal

also includes treatment products for breast-cancer patients and products that assess recurrence risk. *See Puget Sound Business Journal* and *The Seattle Times,* February 14, 2012.

**Agricultural Biotech Raises $65 Million in IPO**

Ceres, Inc., an agricultural biotechnology company based in Thousand Oaks, California, has reportedly raised $65 million in its initial public offering (IPO) after selling 5 million shares of common stock at $13 per share. Goldman, Sachs & Co. and Barclays Capital "acted as joint book-running managers" for the offering, with Piper Jaffray, Raymond James and Simmons & Co. International acting as co-managers, according to Ceres.

Ceres grows and sells proprietary seeds for energy crops used in the production of renewable transportation fuels, electricity and bio-based products. "Its development activities include sweet sorghum, high-biomass sorghum, switchgrass and miscanthus," the company said.

According to a news source, Ceres said in its IPO application to the U.S. Securities and Exchange Commission that it plans to use the funds to extend its operations in Brazil, which has been importing corn ethanol to meet its domestic demands. Ceres will also use $5 million to expand its sales and marketing and business development teams. *See Ceres Press Release* and *Ventura County Star,* February 22, 2012.

**New Program to Provide Accelerated "Speed-to-Market" for Medical Device Entrepreneurs**

The nonprofit Memphis Bioworks Foundation and Innova, a pre-seed, seed and early-stage investor, have announced a program designed to help entrepreneurs bring medical device products and companies to market. Called ZeroTo510, the program is an initiative of the state-funded Greater Memphis Accelerator Consortium, whose mission is to "to accelerate growth of entrepreneurial businesses in the Greater Memphis area."

ZeroTo510 is focused on helping "medical device entrepreneurs navigate the start-up process, refine business models and achieve the Food and Drug Administration's 510(k) pre-market notification filing," according to Bioworks. Through a competitive application process, six startups will be selected to participate in an "intensive, mentor-driven, 12-week program of instruction and hands-on activities designed to guide the entrepreneur through the process." Each of the six companies chosen will receive $50,000 in seed capital from Innova and MB Venture Partners to "jumpstart their finances." Applications are due April 5, 2012.

"ZeroTo510 is the first-ever program of its kind in the United States focused on medical devices," said Allan Daisley, Biowork's director of innovation and

sustainability initiatives. "Typically, it can take years for ideas to pass through regulatory hurdles. An accelerator program that focuses on the 510(k) filing is the right approach to achieving an expedited path to market, but achieving success in that path requires unique skills and knowledge." *See Memphis Bioworks Foundation News Release*, February 14, 2012.

**Mississippi Biotech Moves to University of Maryland BioPark**

Biotech startup Ablitech, Inc. has reportedly relocated its operations from Hattiesburg, Mississippi, to the University of Maryland (UM) BioPark in Baltimore. Ablitech seeks "venture funding and biotechnology partners to advance its patented product, Versadel, into animal and human trials." According to UM, Versadel "is a polymer-based product that carries certain gene silencing bits of genetic material, which can be directed to targets such as cancer cells, while slipping past the body's immune defenses intact."

Ablitech CEO Ken Malone said the company chose the new location because of the "many potential partnerships" in both Baltimore and Maryland. BioPark is a biomedical research park with more than 20 life sciences companies and academic research centers "commercializing new drugs, diagnostics, and devices and advancing biomedical research." *See UM Press Release*, January 26, 2012.

## BUSINESS CLIMATE

**BIO Survey Claims Investors Optimistic About Biotech Investments**

According to a survey recently released by the Biotechnology Industry Organization (BIO), investors believe now is a good time to invest in biotech companies, particularly those dealing in the immunology and oncology fields. Presented at the 14th Annual BIO CEO and Investor Conference, the BIO Investor Perception Survey 2012 also indicates that investors believe the United States provides more investment opportunities than Europe and Asia.

Alan Eisenberg, BIO's executive vice president of emerging companies and business development, reportedly suggested that signs point to an increase in Food and Drug Administration approvals. He noted that 31 new drugs were approved in 2011 and four new ones have already been approved in 2012 for Type 2 diabetes, cystic fibrosis, basal cell carcinoma, and renal cell carcinoma. "Investors, on a relative basis this year, are more focused on early stage companies than later," Eisenberg said. "And this sentiment is also borne out by the increase in percentage of investors who indicate that they are willing to invest in small market cap biotechs." *See Bloomberg BNA Life Sciences Law & Industry Report,* February 24, 2012.

### India's Prime Minister Pledges to Increase R&D Investments in the Sciences

India Prime Minister Manmohan Singh has reportedly pledged to increase research and development investments in the scientific sector from $3 billion in 2011 to $8 billion by 2017. By creating elite research institutions, bringing Indian scientists back to the country, enriching science education, and equipping state-of-the-art laboratories, the government hopes to "induce the private sector to increase [its] spending on science and technology," according to Singh. Among the projects expected to benefit immediately from the surge in financing is South Asia's first biosafety level-4 lab, which will handle the most dangerous pathogens; located in Pune, the lab will reportedly begin operating this spring.

According to a focus piece in *Science* magazine, Indian researchers have faced many obstacles, including government red tape, corrupt universities, delayed delivery of scientific journals, and insufficient funding. In Bangalore, a $30-million clean lab for nanotechnology is poised to open, and, although financing is not an issue, some scientists involved in the project complain about "supply chain" delays, government limitations on spending for certain materials and onerous reporting obligations. Still, the nation's peer-reviewed publications doubled over the last decade and citation improved from 40 percent to 60 percent of the world average. With a robust economy, some predict that the small numbers of expatriates returning to India may balloon as Western nations continue to cope with a recession. Higher salaries and money readily available to start labs will accelerate that process, according to some. *See Science*, February 24, 2012.

## LEGISLATIVE AND REGULATORY DEVELOPMENTS

### FDA Issues Guidance on Drug Shortage Notification Issues

The Food and Drug Administration (FDA) is requesting public comments on a **draft guidance** titled "Notification to FDA of Issues That May Result in a Prescription Drug or Biological Product Shortage." Issued to address "the rising incidence of drug shortages in the United States," the guidance would encourage manufacturers, already required to report certain drug product discontinuances, to voluntarily notify FDA, beyond the statutory reporting mandates, about potential disruptions to the supply of a prescription product that could lead to a shortage. Comments are requested by April 27, 2012.

FDA requests that commenters not submit comments to the guidance docket addressing a related interim final rule on drug shortages that took effect January 18. The agency specifically seeks comments on "the appropriate scope of voluntary reporting of disruptions that may lead to a product shortage or potential disruption in supply," that is, "whether manufacturers of *all* prescription drug and biological products should be encouraged to notify

FDA" about these issues and "whether the Agency should encourage voluntary reporting with regard to only a certain subset of prescription drug and biological products and, if so," which products.

Among other matters, under the draft guidance, FDA would seek voluntary notification about (i) "[p]roduct quality problems, such as the presence of particulates or impurities, microbial contamination, and stability concerns"; (ii) "[i]nterruptions or other adjustments in manufacturing that may adversely affect market supply, such as routine maintenance, that may temporarily halt product or renovation of manufacturing facilities"; (iii) "[l]oss of a production line or production capacity (e.g., machinery failure or malfunction or quality issues related to a cell line)"; and (iv) "[i]mport delays (e.g., shipments detained upon entry to the United States for any reason that may delay delivery to the manufacturing firm)."

## LITIGATION

### Long-Running Gore-Tex Graft Patent Dispute Fractures Federal Circuit Panel

A divided Federal Circuit Court of Appeals panel has upheld a jury verdict of patent validity and willful infringement and affirmed a district court's decision to enhance the damages verdict, thus upholding an award in excess of $371 million and an additional award of $19 million in costs and attorney's fees. ***Bard Peripheral Vascular, Inc. v. W.L. Gore & Assoc., Inc.*, No 2010-1510 (Fed. Cir., decided February 10, 2012)**. The invention at issue, a prosthetic vascular graft, was subject to dispute by the man who made the graft and first conceived its use and the man who was asked to test the graft and was awarded the patent for it after a 28-year interference proceeding involving both men.

According to the court, David Goldfarb tested the materials supplied by the defendant's project manager, Peter Cooper, and determined the optimal microstructure configuration for its use as a blood vessel graft. Because Goldfarb was purportedly the first to reduce the invention to practice and because there was apparently no evidence that Cooper discussed with Goldfarb this configuration of the material, which the court majority found critical to the invention, the court found the patent valid and that the defendant willfully infringed it for years.

The dissenting judge would have reversed, finding that "[t]he infringement trial was fraught with errors of law, misstatements of fact, and confessed perjury" by one of the witnesses. According to the dissent, this witness admitted under oath that he had lied in prior testimony and had falsified affidavits filed with the U.S. Patent Office to support Goldfarb's patent application. The dissent also claimed that an individual who tests a material "provided to him for testing, in the test for which the material was provided,

does not become the inventor of the material and the use for which he tested it, and does not thereby become the owner of the material with the sole right to the use he was invited to test." This judge also noted that the jury was repeatedly told that Cooper and Goldfarb did not communicate and about other matters involving Cooper that he could not refute because he died before the infringement trial.

**Court Determines Patent Law Limitations, Not APA, Apply to Section 154 Extension Matters**

A federal court in Virginia has ruled that a patentee seeking review of a U.S. Patent and Trademark Office (USPTO) determination adjusting a patent term under 35 U.S.C. § 154(b), a provision allowing for the extension of a patent term to account for the delay between the date the patent application is filed and when the patent is ultimately issued, must comply with the time limitations prescribed by patent law and not those set forth in the Administrative Procedure Act (APA). *Janssen Pharmaceutica, N.V. v. Kappos*, No. 11-969 (U.S. Dist. Ct., E.D. Va., Alexandria Div., decided February 10, 2012). The 20-year patent term is ordinarily calculated from the date a patent application is filed, but Congress, recognizing that administrative delay could significantly shorten the patent term, provides for the term to be adjusted.

Here, the patent application was filed on March 14, 2005, and USPTO "issued its first office action concerning the application on April 9, 2007. That office action was rescinded and replaced by a different office action on July 16, 2007." USPTO informed the applicant that it would extend the patent term by 207 days, based on the date of the first office action. "Had the July 16, 2007, 'rescind and replace' date been used, the applicant would have received 98 additional days of PTA [patent term adjustment]." The applicant requested reconsideration arguing that the adjustment should have been based on the later date, and USPTO dismissed that request on May 18, 2010. The patent then issued on June 22, reflecting an extended patent term of 1009 days, again based on the April 9, 2007, action date.

The applicant, now a patentee, filed a petition seeking the USPTO director's review of the dismissal of its request for reconsideration and requesting that the extension be based on the July 16, 2007, date. This petition was dismissed on March 15, 2011. The patentee sought reconsideration of this determination in April, and it was denied on September 6. This ruling stated that it was "a final agency action within the meaning of 5 U.S.C. § 704 for the purposes of seeking judicial review." The patentee then filed a complaint in federal court on September 9, seeking to increase the patent's term by 98 days.

USPTO argued that the action must be dismissed because the patentee failed to comply with 35 U.S.C. § 154(b), which required at the time that the action be filed in the D.C. district court (under the America Invents Act, exclusive

venue has now been given to the Eastern District of Virginia), and because it was time-barred by the section's 180-day statute of limitations. The patentee contended that the venue and timing requirements of section 154 do not apply because it sought review under the Administrative Procedure Act. According to the court, a challenge to the number of days of PTA calculated by the USPTO is governed by section 154, otherwise "the availability of post-issuance administrative review . . . would eviscerate the very limitations on judicial review Congress included in the patent statute."

The court agreed that the matter should have been filed in the D.C. district court. Because that court had recently applied tolling to an action brought under section 154, the Virginia court decided to transfer the case rather than dismiss it to give the D.C. court the opportunity to determine whether the complaint was timely. The patentee contended that the action was timely because it was filed within 180 days of USPTO's March 15, 2011, ruling. USPTO urged the court to determine that the statute of limitations begins to run from the date the patent issues and not from the date of the agency's final PTA determination. The matter was transferred without prejudice to USPTO's argument that the complaint was time-barred.

## NEWS BYTES

The Food and Drug Administration (FDA) releases a **final guide** dated February 2012 titled "Guidance for Industry: Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information." The guidance finalizes draft guidance of the same title dated September 2010.

The Food and Drug Administration (FDA) **announces** the availability of final product-specific bioequivalence (BE) recommendations that "provide product-specific guidance on the design of BE studies to support abbreviated new drug applications." FDA requests comments at any time. The agency also **issues** additional draft and revised draft product-specific BE recommendations. FDA requests comments by April 23, 2012.

The Food and Drug Administration (FDA) **corrects** a docket number appearing in a February 15, 2012, *Federal Register* notice announcing an opportunity for public comment on a proposed collection of information on a potential "biosimilar product and an application for a supplement for a proposed interchangeable product." The corrected number is "[Docket No. FDA–2012–N–0129]." Comments on the **original** notice about section 351(k) biosimilar applications are requested by April 16, 2012.

The U.S. Department of Agriculture **announces** a March 5-6, 2012, meeting in Washington, D.C., of the Advisory Committee on Biotechnology and 21st Century Agriculture (AC21). Agenda items include "progress of the four AC21

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

ISSUE 30 | MARCH 1, 2012

working groups on analyses relevant to the overall AC21 charge [and] how the commercial sector is addressing unintended presence now and managing risk."

## UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Practice Partners Scott Sayler 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. Sayler will also deliver remarks as chair of DRI's Drug and Medical Device Committee.

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