Shook, Hardy & Bacon L.L.P.

ISSUE 83 | AUGUST 21, 2014

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

USPTO Director Addresses IP Issues During Advisory Committee Meeting

In her opening **remarks** during the Patent Public Advisory Committee's August 14, 2014, meeting, U.S. Patent and Trademark Office (USPTO) Deputy Director Michelle Lee referred to the Inspector General's report, summarized in Issue **82** of this *Bulletin*, and defended the agency's telework program. While Lee acknowledged "isolated problems," she noted that the program has been a success, with teleworking employees spending more time examining applications than examiners at headquarters and helping to significantly reduce the backlog of unexamined patent applications. She outlined steps that had been taken to improve the accounting process and educate supervisors and employees on telework policies.

Lee also reported that USPTO anticipates receiving some 600,000 patent applications during the current fiscal year, "an increase of more than five percent over Fiscal Year 2013," and observed, "Our backlog of unexamined patent applications now stands at fewer than 620,000—a decrease of more than 17 percent since 2009, despite an average five percent increase in filings year over year." She further described how Denver's mayor has welcomed visitors traveling through the city's airport by claiming in a public service announcement that the newly opened USPTO satellite office is expected to generate in excess of $400 million in economic activity there.

Agency officials speaking in addition to Lee were slated to address issues including new guidance and training provided to patent examiners in light of recent court rulings, efforts to reduce the Request for Continued Examination backlog, international efforts, updates on the Patent Trial and Appeal Board's work, finance and budget issues, and legislative initiatives.

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INVESTOR NEWS

Government Funding to Support Development of Ebola Treatment

The U.S. National Institute of Allergy and Infectious Diseases has reportedly exercised options to conduct Phase 1 human-safety trials and non-human primate efficacy studies of an intramuscular formulation of BioCryst Pharmaceuticals' BCX4430 to advance its development as a treatment for hemorrhagic fever viruses such as Ebola. The options will provide an additional $4.1 million to the Research Triangle Park-based company as part of a September 2013 grant valued up to $22 million over five years if all options are exercised.

BioCryst Chief Medical Officer William Sheridan said, "The ongoing Ebola epidemic in West Africa emphasizes the urgent need for safe and effective antiviral agents for hemorrhagic fever virus diseases. We look forward to the body of evidence supporting BCX4430 evolving into a highly compelling package, enabling us to attract U.S. government advanced development funding. This is critical so that a new drug application can be filed as quickly as feasible for this unique, broad spectrum antiviral." *See BioCryst Pharmaceuticals, Inc. Press Release*, August 13, 2014.

Molecular Diagnostics Co. Raises $11.8 Million in Funding Round

Castle Biosciences Inc. has reportedly completed an $11.8-million Series E funding round led by new investor HealthQuest Capital. Based in Friendswood, Texas, the molecular diagnostics company has "a portfolio of molecular tests designed to provide tumor-specific information to help determine the best treatment approach in patients diagnosed with uveal melanoma, cutaneous melanoma, esophageal cancer, thymic cancers, mesothelioma, and gliomas." It will use the funds to expand the clinical availability of its portfolio, including DecisionDx-Melanoma, a cutaneous melanoma gene expression profile test. HealthQuest Managing Partner Garheng Kong, who will join Castle Biosciences' board of directors, said that the company's "molecular diagnostic products are an important and exciting advancement in the assessment and treatment of rare and underserved cancers." *See Castle Biosciences Inc. News Release*, August 13, 2014.

Funding Secured to Support NDA for Postmenopausal Osteoporosis Treatment

From its Philadelphia, Pennsylvania, headquarters, Tarsa Therapeutics, Inc. has announced that Oxford Finance and Square 1 Bank have provided a $10-million loan that will be used to support the filing of a new drug application (NDA) with the U.S. Food and Drug Administration for the company's Ostora tablet, an oral recombinant calcitonin treatment for postmenopausal osteoporosis. Tarsa President and CEO David Brand said,

"We believe Ostora may be an attractive therapeutic option for many of the millions of women with osteoporosis who cannot or will not take other therapies." Noting that the drug "is well-tolerated and has been shown to have a positive effect on bone mineral density at the lumbar spine," Brand expressed his appreciation for the support of two financial institutions with experience in the life sciences and venture communities. *See Tarsa Therapeutics, Inc. News Release*, August 13, 2014.

Israeli Biotech Takes Chance on Public Market

Foamix Pharmaceuticals Ltd. has **indicated** in a filing with the U.S. Securities and Exchange Commission that it plans to raise nearly $75 million in an initial public offering.

The Israeli company, which develops topical foam products for use in dermatology and gynecology, has two pipeline products—FMX101 for acne and FMX102 for impetigo—that have completed Phase II studies, and late-stage trials are planned for 2015. According to *FierceBiotech*, it appears that the company believes it can succeed where other biotechs have recently been "hit-or-miss." BioBlast, also headquartered in Israel, reportedly saw its stock drop 35 percent in the first two days of trading. *See FierceBiotech*, August 14, 2014.

Late-Stage Ear Treatment Biotech Raises $100 Million in IPO

Otonomy, Inc., a San Diego, California-based clinical-stage company that focuses on the development and commercialization of inner and middle ear disease therapeutics, has reportedly raised $100 million in an initial public offering (IPO), selling some 6.3 million shares of common stock at the top range of $16 per share. The company has earmarked an additional 937,500 shares for over-allotments, setting the maximum deal value at $115 million. According to a news source, the shares quickly shot up 12 percent when they hit the market, trading at some $18 by mid-morning thus making it one of a short list of biotech companies that have had successful debuts.

The company has apparently indicated that its lead drug, AuriPro (OTO-201), met its primary endpoints in two Phase III trials, and the company expects to submit an application to the U.S. Food and Drug Administration in the first half of 2015. The drug, a sustained-release formulation of ciprofloxacin, has been developed to reduce postoperative complications for pediatric patients who have undergone tube-placement surgery. Additional information about the company appears in Issue **64** of this *Bulletin*. *See FierceBiotech*, August 13, 2014.

Oxford Nanopore to Use $59 Million to Broaden Portfolio and Support Commercialization

U.K.-based Oxford Nanopore Technologies LTD had reportedly raised £35 million (US$59 million) in a private placement of ordinary shares that included new investor The CF Woodford Equity Income Fund. Nanopore CEO Gordon Sanghera said, "These additional funds will allow us to both accelerate and scale the adoption of our MinION™ devices. Our access program for MinION is progressing as expected, and we now need to broaden our product portfolio and deepen our commercial activity." The company specializes in nanopore-based electronic molecular systems that analyze single molecules including DNA, RNA and proteins. Its devices can be tailored to specific high-value sequencing applications and "may be used in scientific research, personalised medicine, crop science, security & defence and environmental applications." Since its 2005 founding, the company has raised £180 million. Further details about the company appear in Issue 66 of this *Bulletin*. *See Oxford Nanopore Technologies LTD Press Release*, August 12, 2014.

U.S. Nonprofit Helps Fund Search for DMD Cure

According to a news source, CureDuchenne, a U.S. national nonprofit seeking a cure for Duchenne Muscular Dystrophy (DMD), will provide up to €5 million (US$7 million) to Prosensa Holding N.V. to support a number of the biotech company's RNA-based therapeutics designed to address unmet medical needs for patients with rare genetic disorders. The organizations have been collaborating since 2004, and the latest infusion of convertible promissory notes is intended to accelerate the development of and patient access to DMD therapies. Located in the Netherlands, Prosensa is currently pursuing a new drug application filing with the U.S. Food and Drug Administration under its accelerated approval pathway for lead DMD therapy, PRO44. It expects to conduct a placebo-controlled trial of the drug in the United States in the first half of 2015.

CureDuchenne Founder and CEO Debra Miller said, "We are very encouraged by the pioneering progress that Prosensa has made in Duchenne and are committed to the long-standing collaboration we have with Prosensa to support the development of treatments for boys diagnosed with this rare and devastating genetic disease. This partnership underscores the important role that patient groups play in accelerating the research and development for Duchenne and other diseases." *See Prosensa Holding N.V. News Release*, August 11, 2014.

BUSINESS CLIMATE

Mexican Health-Care Market Estimated to Gain 6.8 Percent Compounded Annually

Research and consulting firm GlobalData reports that Mexico's health-care market, including both the pharmaceutical and medical device sectors, will be worth about US$27.9 billion by 2020. The overall increase will apparently represent a compound annual growth rate of 6.8 percent from a base of $17.6 billion in 2013. GlobalData attributes the anticipated growth to non-communicable disease prevalence, regulatory improvements, government support for these industries, and the North American Free Trade Agreement. According to GlobalData's Joshua Owide, "Over 350 domestic and multinational companies are engaged in the manufacture of pharmaceutical products in Mexico. . . . During the next five years, the pharmaceutical sector will have the opportunity to expand, due to a number of branded drugs losing market exclusivity." *See GlobalData News Release*, August 7, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FDA Issues Guidance on Unique Medical Device ID System

The U.S. Food and Drug Administration (FDA) has **issued** guidance to help industry, particularly small businesses, label their medical devices in conformity with a September 2013 rule that establishes a unique device identification (UDI) system. The rule requires the labels and device packages of medical devices distributed in the United States to include a UDI, unless the agency grants an exception or alternative to the rule's UDI label requirements. Among other matters, the system is intended to improve the effectiveness of medical device recalls, allow rapid identification of a device to help correct adverse event reports quickly, give medical providers information about the device to reduce medical errors, and standardize the way device use is documented, "leading to a more robust postmarket surveillance system which can be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices." The guidance also includes compliance dates for UDI implementation; they start for certain devices on September 24, 2014, and will require full compliance by 2020.

Physicians Urge FDA to Allow Distinctive Names for Biosimilars

A coalition of organizations representing specialist physicians and individual physicians have **authored** a letter to U.S. Food and Drug Administration (FDA) Commissioner Margaret Hamburg calling on the agency to allow biosimilar drug products to have "distinguishable nonproprietary names."

Noting that biosimilars will not be identical to the reference products, the organizations contend that (i) "[d]istinct nonproprietary names will help to alert physicians that each product, while safe and effective, may differ slightly"; (ii) "allowing physicians to know the exact product that they are prescribing will increase confidence, thus encouraging more robust utilization of biosimilars than may develop without this transparency"; (iii) 61 percent of physicians prescribing biologics and biosimilars in Europe "believed that if two products shared an International Nonproprietary Name (INN), they were approved for all of the same indications," which "is not necessarily the case"; (iii) "distinguishable names will help prevent inappropriate pooling of adverse events"; and (iv) "FDA's decision on interchangeability between indications may largely be rendered moot once biosimilars enter the U.S. marketplace, if the biosimilar shares a nonproprietary name with the reference product."

Among the organizations signing the letter were the Alliance for Patient Access—identified by *The Wall Street Journal* as a group that is "largely funded by the pharmaceutical industry"—American Academy of Dermatology, American College of Rheumatology, and Association of Black Cardiologists. Brand-name drug makers and biotechnology companies reportedly endorse this position on biosimilar naming as well. *See The Wall Street Journal*, August 15, 2014.

LITIGATION

Federal Circuit Rules Jurisdiction Lacking in Vermont Dispute with Patent Assertion Entity

The Federal Circuit Court of Appeals has determined that it lacks jurisdiction to review a district court ruling remanding to state court for lack of federal jurisdiction a lawsuit brought by Vermont's attorney general (AG) against MPHJ Technology Investments, LLC, a purported patent assertion entity, for alleged unfair and deceptive trade practices; the lower court determined that the complaint does not raise a federal-law claim or ques-

tion that would give rise to federal jurisdiction. ***Vermont v. MPHJ Tech. Invs., LLC*, No. 2014-137 (Fed. Cir., order entered August 7, 2014)**. Additional details about the AG's lawsuit appear in Issue **58** of this *Bulletin*. The court also refused to address MPHJ's challenge to the lower court's failure to address its motions to dismiss for lack of personal jurisdiction and for Rule 11 sanctions.

Guilty Plea Entered in Cancer-Drug Smuggling Operation

The owner of an Istanbul, Turkey-based pharmaceutical company has pleaded guilty in a Missouri federal court to charges that he shipped illegal cancer-treatment drugs into the United States. Sabahaddin Akman reportedly faces up to 20 years in prison; he has agreed to pay a $150,000 fine, if imposed by the court, and a $150,000 forfeiture payment to the United States. Akman allegedly used shipping labels to conceal the nature of the shipments, including false customs declarations describing the contents as gifts, and divided large drug shipments into smaller packages to reduce the likelihood of seizures by customs authorities. Some of the drugs Akman shipped to the United States needed constant cold temperatures to maintain stability and effectiveness, but he failed to provide any temperature protection. The drugs allegedly did not meet U.S. Food and Drug Administration (FDA) standards and had not been approved for use in the United States. *See Department of Justice Press Release*, August 12, 2014; *FDA News Release*, August 15, 2014.

Company Seeks SCOTUS Order Allowing Federal Circuit to Apply *Alice* Standard

Advanced Biological Laboratories SA (ABL) has requested in a reply brief that the U.S. Supreme Court (SCOTUS) issue a GVR order—grant its petition for certiorari, vacate the lower court decision and remand for further proceedings—arguing that the Court's *Alice Corp. Pty. Ltd. v. CLS Bank International* ruling establishes a different standard for deciding patent eligibility than the standard used by the Federal Circuit Court of Appeals when it invalidated ABL's patents, which purportedly recite a type of "expert system," i.e., a computer program, that helps physicians select treatments for their patients. *Advanced Biological Labs., SA v. SmartGene, Inc.*, No. 13-1299 (U.S., reply filed August 6, 2014). Additional information about *Alice Corp.*, which was argued before SCOTUS in April 2014 and decided in June, appears in Issue **75** of this *Bulletin*.

ABL also argues that the lower court failed to interpret the claims from the perspective of the "relevant audience," here, computer scientists with knowledge of artificial intelligence technology, and decided the patent-eligibility issue without any record support. According to ABL, the Federal Circuit panel ignored the absence of a record "and simply decided, by fiat, that the claimed invention could be performed by human thought alone," in granting the defendant's motion for summary judgment.

NEWS BYTES

The U.S. Food and Drug Administration (FDA) **seeks** participation proposals for a pilot program involving tools that manufacturers and the agency can use to assess and measure the performance, safety and effectiveness of medical devices. Tool developers may begin submitting nominations for participation in the voluntary Medical Device Development Tools (MDDT) Pilot Program on September 15, 2014. According to FDA, agency-qualified MDDT tools can be "relied upon by the medical device industry in support of their device submission to the Agency, potentially reducing time and other resources needed to develop new products. This proposed voluntary qualification process is intended to enable submitters of MDDT proposals chosen for this pilot program to work closely with FDA to determine the amount and type of evidence and other information needed to support qualification for a specific tool and context of use."

The U.S. Food and Drug Administration (FDA) **requests** comments on draft industry guidance titled "Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act." The **guidance** is apparently "intended to assist sponsors developing biological products, sponsors holding biologics license applications (BLAs), and other interested parties in providing information and data that will help the Agency determine the date of first licensure for a reference product under 351(k)(7)(C) of the Public Health Service Act (PHS Act), as added by the Biologics Price Competition and Innovation At of 2009 (BPCI). The BPCI Act amends the PHS Act and other statutes to create an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product." When finalized, the guidance "will represent the Agency's current thinking on determining the date of first licensure for biological products filed under section 351(a) of the PHS Act," a task that FDA characterizes as presenting "unique challenges." Comments are requested by October 6, 2014.

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The U.S. Food and Drug Administration (FDA) **extends** the comment period on draft guidance titled "Best Practices in Developing Proprietary Names for Drugs," a document intended to help manufacturers develop and select proprietary names in a way that will minimize medication errors. FDA took the action in response to requests for additional time to submit comments, which are now due September 15, 2014.

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