Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Court Rules Patent Attorneys Did Not Infringe Scientific Article Copyrights

In a bench ruling, a federal court in Texas has reportedly determined that patent attorneys did not infringe scientific article copyrights by making copies for use in patent applications, finding that uses associated with patent prosecution are protected under the fair-use doctrine. *Am. Inst. of Physics v. Winstead PC*, No. 12-1230 (U.S. Dist. Ct., N.D. Tex., Dallas Div., decided May 22, 2013). Judge Barbara Lynn had earlier ruled that the law firm did not infringe the copyrights by providing copies to the U.S. Patent and Trademark Office (USPTO) as prior art, but allowed the plaintiffs to amend their complaint to allege that the firm maintains an unlicensed "library" of non-patent literature in violation of copyright law.

The firm denied that it kept such a library or that it profited from incidental copying of articles that its attorneys review while preparing and prosecuting patent applications or send to clients as part of the application process. In this regard, the court reportedly said that it was "unimaginable" that attorneys would be required to remove the articles in a USPTO response to an application before forwarding it to a client and said she would not give the publishers unlimited discovery to "slop around to find something bad" in the law firm's practices. The court will apparently issue a written decision to explain her fair-use analysis and granted the plaintiffs limited discovery on their claim that the firm has infringed its copyrights by sending an article to foreign co-counsel as part of a foreign patent application. She evidently cautioned that countries with patent laws similar to those in the United States—that is, requiring the submission of prior art—would prompt her to issue a similar fair-use ruling.

The plaintiffs, several scientific article publishers, sued other law firms raising similar copyright infringement allegations in Minnesota and Illinois federal courts. Additional information about those suits appears in issues 31, 34 and 37 of this *Bulletin*. *See Law360*, May 22, 2013.

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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

Ophthotech Secures $175 Million to Fund Late-Stage Study on AMD Treatment

New York-based Ophthotech Corp., which develops therapies for treating ophthalmic diseases, has received $175 million in financing that it reportedly plans to use to fund a late-stage study of Fovista™, a treatment for the wet form of age-related macular degeneration (AMD). According to the company, the financing consists of $125 million from Novo A/S, which manages Novo Nordisk Foundation assets said to be valued in excess of $30 billion, in exchange for royalties on future sales of Fovista™, and $50 million in the form of a Series C preferred stock financing from Novo A/S and current venture investors in Ophthotech. Details about the study have not been released, but it is reportedly slated to begin in the third quarter of 2013 and enroll nearly 1,900 patients in more than 200 centers worldwide.

"We are excited to lead this very large financing to drive Phase 3 development of Fovista™," said Henrik Gürtler, Novo A/S CEO. "Ophthotech is well positioned to bring this important drug rapidly to market, based on the strength of Phase 2b results and the proven medical, regulatory and commercial capabilities of its management team." *See Ophthotech Corp. News Release,* May 29, 2013.

eFFECTOR Therapeutics Secures $45 Million in Financing for Cancer Treatment

Biopharmaceutical drug manufacturer eFFECTOR Therapeutics, Inc., which develops small-molecule drugs to block protein synthesis mechanisms required for cancers caused by certain malfunctioning oncogenes, has announced the completion of a $45-million Series A financing round. Headquartered in San Diego, the company reports that the funding will be used to "support multiple discovery programs and enable acquisition of tumor response data in patients for a lead drug candidate."

eFFECTOR Director Larry Lasky said, "eFFECTOR has harnessed a very unique technology and scientific approach in order to pioneer the discovery of selective translation regulators as a new class of therapeutics for cancer and other serious diseases. This approach is a major paradigm shift from targeting disease-triggering mechanisms to a key effector mechanism, and if successfully executed could have a dramatic impact on the treatment of cancer. This is the age of innovation in drug discovery, particularly in oncology. eFFECTOR's is the kind of great science that VCs should be funding to build the pipeline of our next generation of medicines." *See eFFECTOR Therapeutics, Inc. News Release,* May 20, 2013.

Cardeas Pharma Secures $34 Million to Develop Aerosol Antibiotics for Respiratory Infections

Cardeas Pharma Corp., a Seattle-based developer of inhaled antibiotic therapies used to treat multi-drug resistant (MDR), hospital-acquired respiratory infections, has announced that it has secured $34 million in Series B financing from new investors H.I.G. BioVentures, LLC and Delphi Ventures, and existing investors Novo A/S, Avalon Ventures, Devon Park Bioventures and WRF Capital (Washington Research Foundation). According to the company, the proceeds will be used to fund development of its eFlow® InLine Nebulizer system to potentially treat health care- and ventilator-associated pneumonia (HCAP/VAP).

Cardeas CEO Bruce Montgomery said, "We are pleased to have the support of both new and existing investors in this round of financing. It will enable us to complete a Phase 2 safety and efficacy study of our aerosol combination antibiotics as adjunctive therapy to intravenous antibiotics in patients at high risk for multi-drug resistant infections who are on a mechanical ventilator."

Current HCAP/VAP treatment apparently requires intravenous antibiotic therapy that targets Gram-negative and/or Gram-positive bacteria. Cardeas's product aims to "deliver a novel combination of the antibiotics amikacin and fosfomycin as an aerosol formula and is being studied as an adjunctive therapy to treat multi-drug resistant Gram-negative and Gram-positive (including MRSA) pneumonia." *See Cardeas Pharma Corp. News Release,* May 22, 2013.

FAPESP Funds $680 Million for New Multidisciplinary Centers in Brazil

According to news sources, the São Paulo Research Foundation (FAPESP) has pledged $680 million during the next 11 years to fund 17 new Research, Innovation and Dissemination Centers (RIDCs) in Brazil. One-half of the funding, which will reportedly be used for biomedical research, technology transfer initiatives and outreach in such fields as drug discovery and the social science of violence, will reportedly come from FAPESP, with the remainder provided by the host institutions. The recently renamed Human Genome and Stem Cell Research Center (HUG-CELL) at the University of São Paolo is expected to receive approximately $3 million in funding during the first three years.

The RIDC program is designed "to offer funding for research groups which have especially bold scientific proposals that require funding for a long time," FAPESP Scientific Director Carlos Henrique de Brito Cruz was quoted as saying. Each RIDC is reportedly expected to establish a research hub in its focus area, seek out and develop opportunities to have its research results contribute to commercially or socially relevant high-impact areas, and spread knowledge. *See GenomeWeb Daily News,* May 23, 2013; *ScienceInsider,* May 24, 2013.

BUSINESS CLIMATE

U.S. Biotech Sector Shows IPO Gains in 2013

According to *Reuters*, 14 biotech companies have gone public so far in 2013, marking a possible turnaround for the sector with a rising stock market, low interest rates and an absence of market volatility apparently making high-risk investments more palatable to investors. These initial public offerings (IPOs), the best start in six years, have brought strong average returns of about 20 percent, compared to 16 percent gains across all industries.

Meanwhile, a new PricewaterhouseCoopers/National Venture Capital Association MoneyTree™ report, based on Thomson Reuters data, shows that venture investments in some biotechnology specialties, such as early-stage biosensor companies, soared some 152 percent in the first quarter of 2013. Animal biotech businesses also reportedly experienced a more-than-doubling of investments and biotech research companies posted a 37 percent jump over 2012. *See Genetic Engineering & Biotechnology News*, May 15, 2013; *Reuters*, May 22, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FDA Seeks Premarket Notification for Mobile Medical Application

The U.S. Food and Drug Administration (FDA) has informed an India-based company that it is expected to file a premarket notification as to its uChek Urine analyzer, software currently for sale on Apple Inc.'s App Store for the screening of diabetes and urinary tract infections. In its May 21, 2013, **letter**, FDA notes that while the application (app) refers to urinalysis dipsticks that have been cleared for use, "they are only cleared when interpreted by direct visual reading. Since your app allows a mobile phone to analyze the dipsticks, the phone and device as a whole function[] as an automated strip reader," thus making the app a medical device under the Food, Drug, and Cosmetic Act, according to FDA.

CRS Issues Report on Compounded Drugs

The Congressional Research Service (CRS) has issued a **report** titled "Compounded Drugs" to address the risks and oversight issues raised by the growing volume of drugs produced through nontraditional compounding—that is, outside the context of a pharmacist creating a prescription in consultation with a licensed health provider to treat a specific patient. Among other matters, the report examines the 2012 fungal meningitis outbreak traced to a compounding pharmacy, recent recalls, information about the compounded drugs currently produced, who is producing them, and informa-

tion on adverse events. CRS prepared the report in response to policymaker questions about how best to ensure the safety of compounded drugs given the traditional state role in regulating pharmacies and the lack of any federal requirements for adverse event reporting in this sector.

Industry Experts Meet in Russia to Discuss Harmonized Biologic Regulations

Regulators and representatives of Russia's drug industry met recently with the goal of developing an outline of standards for the evaluation and registration of biotherapeutic and biosimilar medicines, which until now have been unregulated in Russia. The meeting, evidently the first of its kind to take place in the country, was co-hosted by the Association of International Pharmaceutical Manufacturers (AIPM) and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and included representatives from Russia, Belarus, Kazakhstan, Ukraine, the World Health Organization, Health Canada, several European national regulatory agencies, and industry to discuss current challenges in regulating biotherapeutic and biosimilar medicines and exchange global best practices.

Elena Maksimkina, director of the Russian Health Care Ministry's Department for State Control over Drug Circulation, stressed how important it is to cooperate with international organizations. She said, "At present we are introducing the definition of biosimilar medicines into legislation and discussing the respective standards and rules of regulation, which include the issues of interchangeability; choice of reference drug for evaluation; etc. Being a supranational body, the World Health Organization is a leading expert in this field. Now we have a chance to take the best international practices as a basis for developing Russian criteria for biosimilar medicines evaluation." *See Association of International Pharmaceutical Manufacturers News Release,* May 16, 2013.

LITIGATION

Federal Circuit Applies *Gunn,* Rules False Statement About Patent Claim Belongs in State Court

The Federal Circuit Court of Appeals has determined that a dispute over allegedly false statements about patents did not raise a substantial question of federal patent law and thus the federal courts lacked jurisdiction to hear the dispute; the case was remanded to the district court with instructions to remand the matter to New Hampshire state court. ***Forrester Envtl. Servs., Inc. v. Wheelbrator Techs., Inc.*, No. 2012-1686 (Fed. Cir., decided May 16, 2013)**.

While the Federal Circuit opined that prior cases raising a similar issue may well have survived a jurisdictional challenge under *Gunn v. Minton*, 133 S. Ct. 1059 (2013), in which the U.S. Supreme Court ruled that a legal malpractice

claim related to a patent matter belonged in state court, this case did not involve activities that could infringe U.S. patent rights. At issue were statements made by the defendant, one of the plaintiff's competitors, allegedly resulting in the plaintiff's loss of a customer in Taiwan.

According to the court, the allegedly inaccurate statements concerned conduct taking place entirely in Taiwan. "The use of a patented process outside the United States is not an act of patent infringement." And because no product made with a U.S. patented process would be imported into the United States "there is no prospect of a future U.S. infringement suit arising out of [the customer's use of the patented process] in Taiwan, and accordingly no prospect of inconsistent judgments between state and federal courts. . . . Here, as in *Gunn*, the potential conflict is purely 'hypothetical.'"

Vermont AG Brings "Patent Troll" Lawsuit

To protect small businesses and non-profit organizations in the state, Vermont Attorney General (AG) Bill Sorrell has filed a lawsuit seeking to enjoin MPHJ Technology Investments, LLC from purportedly demanding that these entities pay $1,000 per employee for a license to use the company's patent "on the process of scanning documents and attaching them to email via a network." ***Vermont v. MPHJ Tech. Invs., LLC*, No. 282-5-13-Wncu (Vt. Super. Ct., filed May 22, 2013)**.

According to the complaint, the defendant "has engaged in unfair and deceptive acts" and "operates in Vermont through forty wholly owned shell subsidiary companies" each of which "claims to be located at 40 East Main Street, #19, Newark, Delaware 19711, a UPS store." The AG also alleges that the patents the defendant claims to own and refers to in its letters to state businesses and non-profits "were previously the subject of litigation brought by the prior owner of the patents. Those lawsuits were voluntarily dismissed by the patent-holder prior to any determination of their validity. No court has ruled on the validity of the patents."

In addition to permanent injunctive relief, the AG seeks restitution, civil penalties of up to $10,000 for each violation of the state's Consumer Protection Act, and investigative and litigation costs and fees. According to the AG, the Vermont Legislature recently passed "first-in-the-nation legislation creating a new tool for targets of patent trolling and for the Attorney General to address the issue." As expected, Governor Peter Shumlin (D) signed the law (H. 299, **Act No. 0044**), which, among other matters, addresses bad faith assertions of patent infringement. *See Office of the (Vermont) Attorney General Press Release*, May 22, 2013.

Meanwhile, the Electronic Frontier Foundation (EFF), an organization that brings or defends lawsuits to protect the digital rights of consumers and the general public, has launched a **campaign** "to bust a key patent being used to threaten podcasters." According to EFF, Personal Audio LLC has sued a number of podcasters and issued demand letters to small podcasting operations to enforce patents after having

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"tried and failed at its attempt to make an audio player." EFF seeks donations and podcasting prior art—publications from before October 2, 1996—"that disclose similar or identical ideas." EFF apparently plans to bring an *inter partes* review proceeding before the U.S. Patent and Trademark Office to invalidate the patents.

NEWS BYTES

The U.S. Patent and Trademark Office **creates** the After Final Consideration Pilot Program 2.0 which modifies and extends a program designed to increase collaboration between patent applicants and examiners "to effectively advance the prosecution of the application" without resort to a request for continued examination. The program runs from May 19 to September 30, 2013.

The U.S. Patent and Trademark Office **estimates** and seeks public comment on the costs and burdens of various information collections related to procedures for actions taken after a patent is issued, such as requests to correct "errors in issued patents, to submit applications for reissue patents, and to submit issue fee payments." Comments are requested by July 30, 2013.

The U.S. Food and Drug Administration (FDA) **issues** draft guidance on contract manufacturing. Titled "Contract Manufacturing Arrangements for Drugs: Quality Agreements," the guidance describes the agency's "current thinking on defining, establishing, and documenting the responsibilities of each party (or all parties) involved in the contract manufacturing of drugs subject to Current Good Manufacturing Practice (CGMP). In particular, [FDA] describe[s] how parties involving in the contract manufacturing of drugs can utilize Quality Agreements to delineate their responsibilities and assure drug quality, safety, and efficacy." Comments are requested by July 29, 2013.

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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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