Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

RICO Suit Filed Against Alleged "Patent Troll"

Internet entrepreneur Kevin O'Connor's company has filed a Federal Racketeering Influenced and Corrupt Organizations Act (RICO) lawsuit against the individuals and companies that allegedly conspired to extort licensing fees through baseless patent-infringement lawsuits against his startup, FindTheBest.com, and some 20 other purported "victims." *FindTheBest.com v. Lumen View Tech. LLC*, No. 13-6521 (U.S. Dist. Ct., S.D.N.Y., filed September 16, 2013).

According to the complaint, the individual defendants co-invented a patent titled "System and Method for Facilitating Bilateral and Multilateral Decision-Making" that creates an optimal meeting point for two or more individuals, who have provided and ranked their preferences online. They then allegedly licensed the patent to a company formed for the purpose of filing lawsuits against alleged infringers to extort payments for licenses to the patent. They allegedly formed a series of other companies, also non-practicing or "shell" entities, that "are undercapitalized, do not operate any legitimate business, and do not have any actual offices . . . [and thus] avoid numerous burdens of litigation—*e.g.*, the disruption to business and the expense of compiling discovery responses—which they inflict on their victims." The plaintiff claims that the lawsuits are baseless and are filed without "any meaningful pre-filing investigation," and asserts that its online process actually involves non-infringing unilateral decision-making, in which one individual provides preferences.

The complaint outlines how the defendants attempt to intimidate their "victims," including threats that full-scale litigation will involve a demand for burdensome discovery—electronically stored information, both accessible and inaccessible, from the preceding six years, as well as personal data and information unrelated to the suit—and possible targeting of the plaintiff's customers. The plaintiff further outlines telephone conversations that revealed how little the defendants or their counsel understood

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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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the technology it used for its Website service. Following a conversation with one of the individual defendants, the plaintiff claims that defendant Lumen View Technology's lawyer contacted its lawyer "and stated that [the plaintiff's] CEO called [one individual defendant] a 'patent troll.' According to Lumen's attorney, calling someone a 'patent troll' constituted a 'hate crime' under 'Ninth Circuit precedent'" and would be reported to the court absent an apology, financial compensation and settlement of the patent-infringement litigation by payment of a licensing fee.

Alleging RICO violations, extortion, mail fraud, conspiracy, abuse of process, and unfair or fraudulent business acts under California law, the plaintiff seeks general, restitutionary and treble damages; interest; attorney's fees; costs; and injunctive relief. According to news sources, O'Connor, who made his fortune as the co-founder of a business sold to Google for $3.1 billion, has reportedly pledged $1 million of his personal fortune to defend his company. An Illinois court reportedly dismissed similar racketeering claims against another non-practicing entity in February of this year. *See arstechnica.com*, September 16, 2013; *Law360* and *The Washington Post*, September 17, 2013.

INVESTOR NEWS

Biofuel Developer Secures $19.4 Million for Production Facility

Biofuel technology developer Cool Planet Energy Systems has raised $19.4 million in the second closing of a Series D financing round, bringing the total amount raised to $60 million.

The funds will reportedly be used to finalize development of the Greenwood Village, Colorado-based company's first commercial facility—a gasoline plant in Louisiana that will produce high-octane cellulosic gasoline and soil-enhancing biochar from wood biomass. The plant is expected to be operational by the end of 2014.

"While equity markets remain closed to most biofuel businesses, investors are seeing a differentiated opportunity in Cool Planet," said CEO Howard Janzen. "Our drop-in cellulosic gasoline and biochar technology has global potential." Investors from Hong Kong, Singapore, the United Arab Emirates, and Mexico participated in the round, joining existing investors, including North Bridge Venture Partners, Shea Ventures, Google Ventures, and Energy Technology Ventures. *See Cool Planet Energy Systems News Release,* September 17, 2013.

Molecular Diagnostics Company Nets $27.7 Million from Common Stock Offering

Illinois-based Nanosphere, Inc. has reportedly closed a public offering of more than 17 million shares of common stock at $1.75 per share, including 2,250,000 shares that were part of an over-allotment option exercised in full by the underwriters. The company's Verigene® System uses proprietary gold nanoparticle chemistry to achieve "highly sensitive, highly specific molecular diagnostic results through low-cost multiplexing." The system can apparently detect infectious pathogens and drug resistance markers by mapping bacterium genomes. The company, which will use the net proceeds of the sale for general corporate purposes and working capital, currently employs Verigene® to target infections of the bloodstream and respiratory and gastrointestinal tracts. *See Nanosphere, Inc. Press Release*, September 18, 2013.

Aerie Pharmaceuticals Seeks to Raise $58 Million in IPO to Advance Glaucoma Drug

Aerie Pharmaceuticals, Inc., has **filed** a Form S-1 registration statement with the U.S. Securities and Exchange Commission outlining its plans to raise nearly $58 million through an initial public offering (IPO). The Bedminster, New Jersey-based developer of glaucoma drugs reportedly plans to use the funds to build a sales force, move one glaucoma drug candidate known as AR-13324 through a late-stage clinical trial, and another, PG324, through a Phase 2b study. RBC Capital Markets and Stifel Nicolaus & Co. will serve as joint book-running managers for the offering, and Lazard Capital Markets and Canaccord Genuity will serve as co-managers.

According to a news source, if the company's clinical trials succeed, it plans to commercialize a group of drugs to treat glaucoma—a condition in which fluid builds inside the eye, putting pressure on and ultimately damaging the optic nerve. *See Aerie Pharmaceuticals, Inc. News Release,* September 17, 2013; *xconomy.com,* September 18, 2013.

Cancer Diagnostics Company Increases IPO Goal

Since announcing the terms for its initial public offering (IPO) earlier in September, Foundation Medicine, Inc. has reportedly boosted its goal from $75 million to $77.4 million. The Cambridge, Massachusetts-based molecular diagnostics company will use the proceeds, in part, to increase its sales force and support ongoing and new clinical studies. The company's molecular information platform provides physicians with actionable genomic information about their cancer patients, enabling optimized treatment and the development of targeted oncology treatments. In

its amended Form S-1 filed with the Securities and Exchange Commission, the company indicated that it planned to offer 5 million shares at a price between $14 and $16 per share. It has also granted underwriters an option to purchase up to an additional 750,000 shares of common stock. *See Renaissance Capital*, September 12, 2013; *GenomeWeb.com*, September 23, 2013.

BUSINESS CLIMATE

Pharma and Biotech Stocks Rise, M&A and IPO Values Strong, Licensing Deals Down

Market analysts commenting on the dramatic rise in the Nasdaq Biotech Index (up 27%) and the Dow Jones US Pharma Index (up 21%) in the first half of 2013, as well as a significant increase in initial public offerings during that period compared to all of 2012, caution that the economic picture is mixed, with licensing deals off the 2012 rate which was the slowest in five years. Still, mergers and acquisitions (M&A) are on a solid pace at $29 billion between January and June, and later-stage deals have apparently been active, with 32 providing $434 million in up-front payments and $3.2 billion in total deal values. According to the EP Vantage "Pharma Half-Year Review 2013" report, venture capital gravitated toward biotechs with demonstrable science, which could indicate that early-stage biotechs continue to find it difficult to raise this type of financing.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

House Bill Aims to Increase FDA Oversight of Drug Compounding Pharmacies

Joining bills already pending before the U.S. House and Senate, the Compounding Clarity Act of 2013 (**H.R. 3089**) would strengthen the Food and Drug Administration's (FDA) oversight of drug compounding pharmacies. According to sponsor Rep. H. Morgan Griffith (R-Va.), the bill would protect traditional pharmacies, which would remain under the jurisdiction of state pharmacy boards, while subjecting large-scale compounding entities, "or outsourcing facilities," to federal requirements. The legislative concerns about compounders follow a deadly nationwide meningitis outbreak traced to contaminated drugs packaged and distributed by large-scale compounder New England Compounding Center. Additional information about pending Senate legislation appears in Issue **61** of this *Bulletin*. *See Rep. H. Morgan Griffith Press Release*, September 12, 2013.

Rider to Stopgap Funding Bill Would Extend Law on GM Crops

The U.S. House of Representatives has reportedly approved, as part of a stopgap bill that would fund the federal government through December 15, 2013, a rider that would extend for 11 weeks a provision that allows farmers to continue growing genetically modified (GM) crops even if federal approval of their planting is challenged in court. That provision is apparently set to expire at the end of September. GM crop opponents complain that the law interferes with court review of federal agency decisions on GM crop safety and was enacted without appropriate debate when the House and Senate last negotiated federal budgetary issues. *See Reuters*, September 20, 2013.

GPhA Petitions FDA on Biosimilar Naming Standard

The Generic Pharmaceutical Association (GPhA) has requested in a citizen **petition** filed with the U.S. Food and Drug Administration that the agency implement its International Non-proprietary Naming (INN) system policy "equally to all biologics," including biosimilar drug products. GPhA justified its request by claiming that biopharmaceuticals, "by definition . . . are 'highly similar' to the reference biologics and have no clinically meaningful differences that require a unique name." According to GPhA CEO and President Ralph Neas, "This approach works in Europe, it has worked in the United States for chemical drugs, and it should be the standard worldwide. To upset the naming system in place risks engendering confusion and would have a major negative impact throughout the global pharmaceutical supply chain, potentially jeopardizing patient access across the globe."

The association contends that FDA outlined its biosimilars naming policy in a paper submitted to the World Health Organization (WHO) in 2006, in support of current WHO naming conventions. FDA apparently stated at that time that non-proprietary names should be used to communicate interchangeability, rejecting distinctive INN designations for biosimilars. *See GPhA Press Release*, September 19, 2013.

Medical Device Identification System Rule Finalized

The U.S. Food and Drug Administration (FDA) has adopted a final **rule** establishing a unique device identification system (UDI) that will "provide a consistent way to identify medical devices." According to FDA, the UDI system "builds on current device industry standards and processes, and reflects substantial input from the clinical community and the device industry during all phases of its development."

It consists of two components: a unique number assigned by the device manufacturer to the version or model of the device, including production-specific information "such as the product's lot or batch number, expiration date, and manufacturing date when that information appears on the label"; and a publicly searchable database—the Global Unique Device Identification Database—that FDA will administer to serve as "a reference catalogue for every device with an identifier." The database will not store any identifying patient information.

Within one year, high-risk medical devices (Class III), in general, "will be required to carry unique device identifiers on their label and packaging . . . and corresponding device information must be submitted to the new database." Most manufacturers of moderate risk (Class II) devices will have three years to comply, and Class I device manufacturers "not exempt from UDI requirements will have five years to act." The agency has also issued draft industry **guidance** that explains how to submit information to the new database. Comments on the draft are requested by November 25, 2013. *See FDA News Release*, September 20, 2013; *Federal Register*, September 24, 2013.

FDA Issues Final Guidance on Mobile Medical Apps

With an oversight focus on those who develop mobile medical applications (apps) that are intended to be used as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device, the U.S. Food and Drug Administration (FDA) has issued final **guidance** for industry and FDA staff. Those apps undergoing FDA review must comply with "the same regulatory standards" applied to medical devices, and FDA will assess them with the same "risk-based approach that the agency applies to other medical devices."

Noting that it "does not regulate the sale or general consumer use of smartphones or tablets nor does it regulate mobile app distributors such as the 'iTunes App store' or the 'Google Play store,'" FDA will not enforce Food, Drug, and Cosmetic Act requirements as to "the majority of mobile apps as they pose minimal risk to consumers" According to its September 23, 2013, press release, FDA "has cleared about 100 mobile medical applications over the past decade; about 40 of those were cleared in the past two years."

LITIGATION

Federal Court Finds Alleged Reputational Damage Sufficient for Standing

A federal court in Florida has determined that the assertion of a purely reputational interest by a periodontist and implant surgeon who filed an action to correct dental implant system patents by naming him as an inventor is sufficient to confer standing for a § 256 claim. ***Krauser v. Evollution IP Holdings, Inc.*, No. 12-80977 (U.S. Dist. Ct., S.D. Fla., decided September 19, 2013)**. The Federal Circuit Court of Appeals has not yet taken a position on this particular issue, and other courts have rendered conflicting rulings.

Plaintiff Jack Krauser had filed a previous claim against one of the defendants, seeking a declaration that he was both the inventor and owner of the system. The inventorship claim was voluntarily dismissed without prejudice, and the court ruled on summary judgment that Krauser had no ownership rights to the dental implant system. In the case at bar, the defendants argue in their motion to dismiss that Krauser's claims are barred by the doctrine of *res judicata*, he is collaterally stopped from asserting any ownership interest in the patents, his alleged reputational injury is insufficient to establish Article III standing, and defendant Evollution is not subject to personal jurisdiction in Florida.

Because the circuit in which the court sits has adopted a declaratory judgment exception to *res judicata*, under which the "ordinary principles" of the doctrine are not applied if declaratory relief was the only relief sought in the prior action, the court had to decide whether Krauser's request for attorney's fees, in addition to a declaratory judgment, constituted coercive relief and thus barred application of the exception. Under Florida law, attorney's fees are simply ancillary to a claim for damages, so the court found that the exception applied, "the preclusive effect of the Court's declaration in the prior action is limited to the subject matter of the declaratory relief" and issues that could have been raised in the earlier proceeding were not precluded. While ownership had previously been litigated and decided, a claim for correction of inventorship had not, and, according to the court, "it is well established that ownership and inventorship are separate issues."

As to reputational injury, the court examined defamation law to conclude that "Krauser has a vindicatory interest in correcting inventorship because, consistent with common law rationale, an erroneous patent application is *itself* an injury to his reputation sufficient to confer Article III standing. He need not prove any concrete financial or economic injury to vindicate his reputation because, as in most defamation cases, such injuries will generally be impossible to prove, and success on the § 256 inventorship

claim serves a vindicatory purpose even if there is no concrete injury to be redressed. To hold otherwise would mean that the *true* inventor of a product who lacked any economic or ownership interest in his product would have no means of redress. Notwithstanding the contrary case law set forth above, this Court finds such a result untenable."

The court agreed to dismiss Evollution from the suit, finding insufficient contacts under Florida's long-arm statute to exercise jurisdiction over the company. In this regard, the court rejected Krauser's assertion that the company availed itself of the privilege of conducting activities in Florida through its licensing agreement with co-defendant BioHorizons. Still, the court declined to transfer the matter to Delaware, stating "The Court's lack of personal jurisdiction over Evollution is not a sufficient reason to require Dr. Krauser to proceed against BioHorizons—over which the Court does have jurisdiction—in another venue which Dr. Krauser may find inconvenient."

Settlement Reached in Drug Contamination Suit

According to a news source, Nordion Inc. has settled a lawsuit in which Bioaxone Biosciences Inc. sought $90 million for the alleged contamination of a spinal cord injury drug with animal products posing a risk of mad cow disease. *Bioaxone Biosciences Inc. v. Nordion U.S. Inc.*, 12-60739 (U.S. Dist. Ct., S.D. Fla., order entered September 19, 2013). Additional details about the case appear in Issue **34** of this *Bulletin*. The drug was declared adulterated by the Food and Drug Administration and never approved for use in humans. Despite a contract between the plaintiff and defendant specifying that no animal products be used in the creation of the cell bank used to test and develop the defendant's drug, the defendant allegedly incorporated into the cell bank a raw material containing beef extract and chicken feathers. *See Law360,* September 23, 2013.

NEWS BYTES

The National Institutes of Health (NIH) **seeks** comments on its draft Genomic Data Sharing (GDS) Policy that outlines the responsibilities of investigators and institutions when submitting nonhuman and human genomic data to NIH. The GDS Policy also describes the use of controlled-access data and provides expectations regarding intellectual property. Comments must be submitted within 60 days of the September 20, 2013, *Federal Register* publication date.

The U.S. Food and Drug Administration **schedules** a public workshop titled "Complex Issues in Developing Medical Devices for Pediatric Patients Affected by Rare Diseases," organized by the Center for Devices and Radiological Health and Office of Orphan Products Development. It will

be held in conjunction with the Center for Drug Evaluation and Research's workshop, "Complex Issues in Developing Drug and Biological Products for Rare Diseases." Among the topics planned for discussion at the January 8, 2014, workshop are (i) current clinical practices, (ii) specialty practice areas, (iii) clinical trials, (iv) device-related issues for diagnostic devices, and (v) advancing development. Those wishing to participate should register by December 6. The workshop will also be available via streaming Webcast.

The U.S. Food and Drug Administration (FDA) **slates** a public workshop titled "Complex Issues in Developing Drug and Biological Products for Rare Diseases," for January 6-7, 2014. FDA hopes that input from the workshop will help develop a strategic plan to encourage and accelerate the development of new therapies for rare diseases. Discussion will include (i) "complex issues in clinical trials for developing drug and biological products for rare diseases, including endpoint development and selection, use of surrogate endpoints and the accelerated approval pathway, clinical trial design, conduct and analysis, safety considerations, and dose selection"; and (ii) "ways to encourage and accelerate the development of new therapies for pediatric rare diseases." Participants should register by December 20. The workshop will also be available via streaming Webcast.

The U.S. Food and Drug Administration (FDA) **announces** the availability of draft guidance for industry titled "Endocrine Disruption Potential of Drugs: Nonclinical Evaluation." The document is intended to describe which parameters should be assessed in toxicology studies for investigational new drug applications, new drug applications and biologics license applications "regulated by the Center for Drug Evaluation and Research to determine the potential for a drug to disrupt the endocrine system." It also discusses factors to consider when determining the need for additional studies to characterize a drug's potential endocrine disruptor properties. Comments are requested by November 19, 2013.

The U.S. Food and Drug Administration **seeks** comments on the estimated reporting burdens of an information collection arising from the Food, Drug, and Cosmetic Act requirement that all new drug application applicants and those filing an amendment or supplement submit "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Comments are requested by October 17, 2013.

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UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Data Security & Privacy Practice Partners Amor Esteban and Al Saikali will participate in The Sedona Conference® on Cyber Liability slated for October 24-25, 2013, in Del Mar, California. Co-chaired by Esteban, who also leads The Sedona Conference® Working Group 6 on Cross-Border Discovery and Data Protection, the conference will address, among other things, (i) "the current state of the law regarding data security and privacy," (ii) "responding to data breach incidents," (iii) "regulatory responses to data breach incidents," and (iv) "protecting valuable intellectual property in a global cyber environment." Saikali will serve on two panels discussing civil data breach litigation and data security in the health care, pharmaceutical and biotechnology industries.

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