ISSUE 81 | JULY 17, 2014

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

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FIRM NEWS

Dunne to Discuss OTC Drug Issues During ACI Annual Forum

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Debra Dunne** will **join** a distinguished faculty in New York City on October 27-28, 2014, during the American Conference Institute's (ACI's) "3rd Annual Legal Regulatory and Compliance Forum on Over the Counter Drugs." Dunne will participate in a panel discussion on "Modernizing the Monograph system and the OTC Drug Review Process: Seeking Clarity in Uncertainty." Joining her will be in-house global regulatory affairs director for C.B. Fleet Co. and an official with the U.S. Pharmacopeial Convention.

IP NEWS

Patent Damage Awards Studied

Legal analytics firm Lex Machina has **issued** a "Patent Litigation Damages Report" that analyzes patent litigation damages awarded in U.S. district court cases filed between January 1, 2000, and December 31, 2013. While some blockbuster damage awards have occurred in recent years, the report found that "[o]ut of 36,629 patent cases filed and terminated from 2000 through 2013, only 708 cases (1.9%) involved compensatory damage awards." The report explores damages awarded by district, finding "[n]o surprise here for patent litigators: Cases filed in the Eastern District of Texas have generated the most awards of compensatory damages (84 cases), total compensatory damages (over $5 billion of $13 billion national total, or 38%), total reasonable royalty damages ($2.9 billion of $8 billion national total, or 36%), total lost profits damages ($1.4 billion of $2.7 billion national total, or 52%) and total enhanced damages ($232 million of $989 million national total, or 23%) than cases filed in any other district over the past 14 years." The report also names the specific judges who have awarded the most in total compensatory damages, the parties involved and counsel.

Shook, Hardy & Bacon L.L.P.

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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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UK and China Launch Pilot Patent Prosecution Highway Program

The United Kingdom and People's Republic of China have launched a pilot program that will allow applicants who have successfully obtained a patent in one country's intellectual property office to request the accelerated processing of a corresponding application in the other. According to a July 1, 2014, U.K. government press release, "[T]he second office can make use of the work undertaken by the first office to more quickly and efficiently process the application." The pilot U.K.-China Patent Prosecution Highway began on July 1 and will end June 30, 2016.

INVESTOR NEWS

CNS Biotech Prepares $60-Million IPO

Cambridge, Massachusetts-based Sage Therapeutics, Inc., which focuses on developing drugs to treat acute and orphan central nervous system (CNS) disorders, has filed an initial public offering (IPO) to raise about $60 million by selling 4 million shares of common stock priced between $14 and $16 each. An additional $13.6 million could be generated by 600,000 shares to cover overallotments. The company apparently plans to use the proceeds on Phase I and II studies for SAGE-547, a drug that has been developed to treat super-refractory status epilepticus. According to the biotechnology company, CNS disorders constitute 35 percent of the world's disease burden and present "a substantial opportunity for the pharmaceutical industry to innovate." Underwriters include Goldman, Sachs & Co., Leerink Partners, and Canaccord Genuity. *See FierceBiotech*, July 11, 2014.

NIH to Fund Research Centers Targeting Genetic Causes of CHD

The National Institutes of Health (NIH) will award more than $2 million in fiscal year 2015 to research centers that will join the Pediatric Cardiac Genomics Consortium in identifying "genetic causes of human congenital heart disease (CHD) and [relating] genetic variants in patients with CHD to clinical outcomes through collaborative, multi-center studies." Up to five awards will be made for projects than cannot exceed five years, and application budgets are limited to $269,000 in direct costs annually to support research infrastructure. The application due date is October 15, 2014. *See NIH Grants Pediatric Cardiac Genomics Consortium (UM1),* July 8, 2014.

Roka Bioscience Seeks $78 Million to Develop Foodborne Pathogen Diagnostics

With facilities in Warren, New Jersey, and San Diego, California, Roka Bioscience, Inc. has indicated in an amended U.S. Securities and Exchange Commission filing that it plans to offer 5 million shares of common stock at a range of $14 to $16 per share, which could net the company some $67.4 million at the midpoint price. If the underwriters, including Merrill Lynch, Pierce, Fenner & Smith, Leerink Partners, Cowen and Co., and Webush Securities, exercise their overallotment options, the net proceeds would total $77.8 million. Roka develops molecular assays and instrument systems to detect foodborne pathogens, such as *E. coli* 0157:H7, Shiga toxin *E. coli*, *Listeria, Listeria monocytogenes*, and *Salmonella*, for the food-safety industry. *See Genomeweb.com*, July 8, 2014.

Sophia Genetics Raises $13.75 Million in Series B Financing Round

In a Series B financing round led by Invoke Capital, Swisscom and Endeavour Vision, Lausanne, Switzerland-based bioinformatics company Sophia Genetics has reportedly raised $13.75 million to accelerate its entry into European markets. The company focuses on the analysis, interpretation and protection of genetic sequence data in the field of personalized medicine, and, with sophisticated algorithms, provides "the clinical accuracy that is required to provide meaningful, targeted therapies," according to Invoke Capital's Mike Lynch. *See Sophia Genetics News Release*, July 8, 2014.

Silenseed Files IPO Seeking $36.4 Million for Cancer Therapies

Clinical stage biopharmaceutical company Silenseed Ltd. has filed an initial public offering (IPO) with the U.S. Securities and Exchange Commission to raise some $36.4 million that will support its development of proprietary RNA interference-based cancer drugs and delivery systems. Drugs in the Israel-based company's pipeline focus on solid tumor cancers, including pancreatic, prostate and certain brain cancers. The IPO underwriter is Aegis Capital Corp. *See Genomeweb.com*, July 3, 2014.

MRI Diagnostics Co. Registers for $69 Million IPO

T2 Biosystems, Inc. has filed an initial public offering (IPO) worth up to $69 million to support the development of its magnetic resonance imaging (MRI) diagnostic systems. Located in Lexington, Massachusetts, the company is currently seeking U.S. Food and Drug Administration approval under the agency's novel-technologies fast-track process for its T2Dx diagnostic instrument and T2Candida panel, which can apparently

identify five clinically relevant types of a fungal pathogen that is a known cause of sepsis. T2 uses MRI technology to detect infections more rapidly than blood-culture-based diagnostics. *See MassDevice.com*, July 2, 2014.

Sapphire Energy to Work with Sinopec on Algae-Based Biofuels

According to a news source, San Diego-based Sapphire Energy and Sinopec, China's state-owned oil and gas conglomerate, will partner under a flagship U.S.-China EcoPartnerships program to develop and produce algae-based biofuels in China. Sapphire has a research and development facility in Las Cruces, New Mexico, and is currently operating an algal biorefinery in the state. CEO Cynthia "CJ" Warner said during a signing ceremony in Beijing that the partnership "will demonstrate that crude oil from algae can be produced with favorable economics; that it can be integrated into existing fuels distribution networks; and that it will deliver substantial advantages for the reduction of CO2 emissions in both nations." *See Sapphire Energy News Release* and *xconomy.com,* July 10, 2014.

BUSINESS CLIMATE

Lay-off Pace Slows for Biopharma in First Half of 2014

According to outplacement company Challenger, Gray & Christmas, Inc., job cut announcements for the first half of 2014 in the pharmaceutical industry, at 4,215, were one-third less than the comparable period in 2013, at 6,709. Some suggest that the slowdown can be attributed to the decreasing numbers of blockbuster drugs losing their patent protection. While drugs representing about $50 billion in total annual sales will go off the "patent cliff" in 2014, this is far less than the $117 billion loss in sales during 2011-2013. Still, more medicines will lose protection in 2016-2018, leading one commentator to call this "the calm between waves of job reductions." *See Challenger, Gray & Christmas, Inc. Press Release*, July 3, 2014; *Genetic Engineering & Biotechnology News*, July 11, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Executive Advisory Group Recommends Antibiotics R&D Incentives

The U.S. President's Council of Advisors on Science and Technology (PCAST) has reportedly approved a report that endorses a plan to help drug makers develop new antibiotics, part of an overall effort to address antibiotic-resistant pathogens, i.e., the "superbugs" that infect more than

2 million people in the United States annually and are responsible for some 23,000 deaths. Many of the largest pharmaceutical companies have apparently stopped developing antibiotics given high research and development costs and low returns. In response, PCAST has recommended financial incentives and a national infrastructure for new antibiotic clinical trials that would decrease costs for developers. The advisory group has also called on the U.S. Food and Drug Administration to join the fight against antibiotic resistance. The official report will be issued within the next few weeks. *See Fierce Biotech*, July 14, 2014.

Massachusetts Governor Signs Law Increasing Compounding Pharmacy Oversight

Massachusetts Gov. Patrick Duval (D) has signed into law a bill (**H. 4235**) that will impose on compounding pharmacies new licensing, labeling, education, and oversight requirements, as well as penalties and fines for pharmacies failing to comply. Passed unanimously in the House and Senate in the wake of a fungal meningitis outbreak linked to a compounding pharmacy in Framingham, the new law establishes licensing for sterile, complex non-sterile, hospital, and out-of-state pharmacies, requires reporting of adverse drug events, and eliminates any "gray area" between manufacturing and compounding, among other matters. According to the governor, "Every patient deserves to know that the medication they are taking is safe. This law gives Massachusetts the strength and flexibility to better oversee compounding pharmacy practice and protect patients." The law will give the commonwealth's Board of Pharmacy the ability to levy fines of up to $25,000 on violators and the authority to conduct random inspections. *See Gov. Patrick Duval Press Release*, July 10, 2014.

LITIGATION

AIA Did Not Constitute a Pardon for Past False-Marking Acts

The Federal Circuit Court of Appeals has dismissed claims that the America Invents Act (AIA), which made significant changes to the false-marking statute on which a plaintiff's claim was based, was an unconstitutional pardon for those who had allegedly violated the law before it was amended and violated the common-law principle that prohibits the use of a pardon to vitiate a *qui tam* action after it has been filed. ***Stauffer v. Brooks Bros. Group, Inc.*, No. 2013-1180 (Fed. Cir, decided July 10, 2014)**. The lawsuit involved claims filed before the AIA was enacted that Brooks Brothers had violated the false-marking statute by marking its bow ties with expired patent numbers.

Finding that it had jurisdiction to consider the appeal because a decision on the merits would likely redress the plaintiff's alleged injury, the court characterized the false-marking statute amendments—eliminating the *qui tam* provisions and allowing only those with a competitive injury to bring a claim, excluding expired patent marking from the false-marking provisions and applying the provisions to pending cases—as "repealing a law, an action undoubtedly within Congress's power." The court also determined that "this is not a case where Congress attempted to set aside an already adjudicated punishment for a specific individual or a group of individuals; rather, Congress repealed the provisions of the false-marking statute that it did not wish to remain in force. The amendments, therefore, do not constitute a pardon."

The court further held that the AIA amendments did not violate a common-law principle because the plaintiff had no vested rights in his pending lawsuit and the AIA amendments are not a pardon. Agreeing that the remainder of the plaintiff's arguments were waived because they were not timely raised, the court did not address them. Accordingly, the court affirmed the dismissal of his suit "for lack of standing due to the elimination of the *qui tam* provision in the false-marking statute."

Challenge to AIA First-to-File Rule Fails for Lack of Standing

Ruling that it had jurisdiction to consider a constitutional challenge to the America Invents Act (AIA), the Federal Circuit Court of Appeals has dismissed the challenge, finding that the plaintiff lacked standing to assert the claims. ***MadStad Eng'g, Inc. v. USPTO,* Nos. 2013-1511, -1512 (Fed. Cir. July 1, 2014)**. Additional details about the case appear in Issues **41** and **42** of this *Bulletin*.

As to its jurisdiction, the Federal Circuit determined that resolution of the constitutional challenge "would require this court to interpret the terms 'inventor' and 'first-inventor-to-file' under the AIA and to assess the interactions between those terms and the use of the term 'Inventor' in the Intellectual Property Clause of the United States Constitution—Article I, Section 8, Clause 8. It will also cause us to address the scope of protections afforded to 'inventors' by the right to bring derivative actions encompassed within the first-inventor-to-file provision of the AIA." These matters, according to the court, are also at the "heart of the parties' dispute" and are "substantial to the current state of patent law," requiring "continued uniform application."

The court agreed with the district court that the company and its owner, a "garage inventor" who holds a patent on a motorcycle windshield, lack standing because "in order for MadStad to actually suffer any injury fairly

traceable to the AIA, an 'acutely attenuated concatenation of events' was required." The company's alleged harms—increased risk of computer hacking, increased time and effort to file additional patent applications, competitive disadvantage relative to competitors, and lost business and investment opportunities—depended on the company's subjective beliefs and the speculative actions of third parties as well as a series of assumptions about what could to come to pass.

While the court rejected every argument the plaintiffs advanced, it refused to adopt the government's standard that, to establish standing, "MadStad must not only have an invention that is ready for patenting and file an application for a patent on that invention, but must also be faced with a rejection based on an earlier filed application on that same invention and lose a derivation proceeding he initiates to challenge that earlier filing." Still, the court found that, on the record, "MadStad has not established standing based on its fear of being forced into filing a patent application sooner than it would prefer or would normally do."

Federal Court Enjoins Enforcement of Massachusetts Opioid Regulations

A federal court in Massachusetts has issued a preliminary injunction in a challenge to the commonwealth's regulation of a specific opioid analgesic—Zohydro—and denied the commonwealth's motion to dismiss without prejudice. *Zogenix v. Patrick*, No. 14-11689 (U.S. Dist. Ct., D. Mass., decided July 8, 2014). Details about the court's previous ruling enjoining a ban on the painkiller appear in Issue **76** of this *Bulletin*. Information about regulations the commonwealth imposed after the court enjoined the ban appears in Issue **77** of this *Bulletin*.

The court addressed the company's preemption challenges to regulations requiring that (i) doctors or physician assistants certify that "other pain management treatments have failed" before prescribing the drug, and (ii) only pharmacists may handle Zohydro. In the plaintiff's view, the commonwealth had attempted to limit access to a drug that the U.S. Food and Drug Administration had said should be available. According to the court, the challenged regulations are so vague that it is unclear whether they may be interpreted and enforced in a way that obstructs the federal law's objectives. And without a record of enforcement, "it is unclear whether such an obstacle exists." Still, the court determined that the "plaintiff should not bear the brunt of the defendant's vague regulations, waiting for an adequate record of enforcement to develop while the clock ticks on its three-year exclusivity period."

The court denied the defendants' motion to dismiss, ruling that the plaintiff had stated a plausible claim for relief, and, in allowing the motion to preliminarily enjoin the regulation, the court further ruled that the defendants could seek to lift the injunction if they "provide adequate and constitutional guidance to physicians regarding the prerequisites for prescribing Zohydro in compliance with the regulation." Finding that the plaintiff's sealed declaration that pharmacies will not carry Zohydro was insufficiently detailed, the court ruled that it had not met its burden of proof on the "pharmacist-only regulation," but denied its motion "without prejudice to renewal upon a more detailed submission."

Court Orders Dispute over 23andMe DNA Test Kits to Arbitration

A multidistrict litigation court in California has ordered false-advertising, class-action claims filed against personal genetics company 23andMe to arbitration, finding that, while the company's terms of service (TOS), including the arbitration clause, provided insufficient notice to consumers at the time of purchase and they were procedurally unconscionable for lack of sufficient notice and as a contract of adhesion, they were valid as a post-purchase agreement and not substantively unconscionable. *Tompkins v. 23andMe, Inc.*, No. 13-5682 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered June 25, 2014). So ruling, the court dismissed the claims, finding no concerns about statutes of limitation and noting that the dismissal would render the decision immediately appealable. The court's order applies to a number of class actions that were consolidated for pre-trial proceedings; details about the claims appear in Issues 69 and 71 of this *Bulletin*.

According to the court, hyperlinks to the company's TOS appear throughout its Website, but consumers are not required to actively indicate acceptance until after they have purchased a home DNA test kit and have registered to view its results online. The TOS includes a "Miscellaneous" section that requires the submission of all disputes to arbitration "under the rules and auspices of the American Arbitration Association [AAA]." Addressing whether a valid agreement existed between the parties, the court discussed "shrinkwrap," "clickwrap," and "browsewrap" agreements—those agreements presented either online or after a product purchase, implicitly accepted by the consumer by opening and keeping the product. The court found that the agreement here closely resembled a browsewrap agreement that provided insufficient notice at the time of purchase and was ineffective to bind Website visitors or those who only purchased the kit without creating an account or registering the kit.

Still, the court determined that each plaintiff had accepted the TOS post-purchase and concluded that adequate consideration was provided for the consumer's post-purchase acceptance. In California, "[a] written instrument is presumptive evidence of a consideration," and, in the employment context, a "promise to be bound by the arbitration process itself serves as adequate consideration." In addition, the TOS gave consumers certain rights, such as a "limited license" to use 23andMe's "Services." "Furthermore, in exchange for clicking 'I ACCEPT,' customers received the health and ancestry results from their DNA samples." The court also determined that the TOS resembled a clickwrap agreement and thus provided those registering adequate notice.

Because the arbitration provision was not specific enough as to whether questions of arbitrability, such as unconscionablity, were delegated to an arbitrator, the court determined that it had jurisdiction to decide the matter. The court stated, "[A] bare reference to the AAA rules in 23andMe's online contract does not show that the parties clearly and unmistakably intended to delegate arbitrability," in part because the language used "forces a customer to comprehend the import of the 'rules and auspices' of the AAA; locate those rules independently; determine that the AAA Commercial Rules apply by operation of Rule R-1(a); and then specifically identify Rule R-7(a) to learn of the delegation provision. The possibility that the Consumer Rules might also apply creates an additional ambiguity."

Citing the notice infirmities previously discussed and the take-it-or-leave-it aspects of the TOS, the court found the agreement procedurally unconscionable, but, because the terms were not so unreasonable and one-sided as to "shock the conscience," ruled that it was enforceable.

Oregon Settles Generic Safety Suit with Ranbaxy for $2.3 Million

India-based Ranbaxy Laboratories has reportedly agreed to settle claims that that the manufacturing process for its prescription drugs sold in Oregon failed to comply with federal good manufacturing practices thus violating state consumer protection and pharmacy laws. Oregon Attorney General Ellen Rosenblum said, "Fortunately, no Oregonians are known to have been harmed from these common generic drugs, and all of the products are now off the market." The agreement, worth $2.3 million, requires payments to five Oregon state agencies—the Public Employees Benefits Board, Oregon Department of Corrections, State Accident Insurance Fund Corp., Oregon Youth Authority, and Oregon Health Authority. The company must also make a payment to the state consumer protection fund and the Board of Pharmacy. *See Oregon Department of Justice Press Release*, July 8, 2014.

County Pharmaceutical Disposal Law at Issue Before Ninth Circuit

The Ninth Circuit Court of Appeals has heard oral argument in an appeal challenging an Alameda County, California law that requires pharmaceutical companies to fund the environmentally safe disposal of unused drugs. *Pharm. Research & Mfrs., of Am. v. Cnty. of Alameda*, No. 13-16833 (9th Cir., argued July 11, 2014). In August 2013, a federal district court denied the summary judgment motion filed by industry interests, finding that the law did not violate the U.S. Constitution's Commerce Clause. They claim that the law imposes an unfair burden on out-of-state drug makers and essentially makes them responsible for a local garbage problem.

According to a news source, the three-judge appeals court panel appeared skeptical of the argument, with one judge disagreeing that the ordinance shifted costs to interstate producers and noting that it "shifts the costs to all producers. It just so happens that the majority are in other states." The county, which currently operates some 30 drop-off sites, reportedly estimates the cost of collection and disposal at $500,000, while the companies estimate the costs of compliance at $1.2 million. *See SFGate*, July 11, 2014.

NEWS BYTES

The U.S. Food and Drug Administration **issues** guidance titled "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal, Food, Drug, and Cosmetic Act." This document explains how the agency will apply Section 503A of the Food, Drug, and Cosmetic Act as amended under the Drug Quality and Security Act. Among other matters, it describes conditions that licensed pharmacists and physicians must satisfy in compounding drugs to be exempt from certain sections of the law.

The U.S. Food and Drug Administration **requests** comments on draft guidance titled "Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act." The document sets forth the agency's expectations of outsourcing facilities subject to current good manufacturing practices requirements while the agency develops industry-specific regulations under amendments to the Federal Food, Drug, and Cosmetic Act. Comments should be submitted by September 2, 2014.

The U.S. Food and Drug Administration **reopens** the comment period for a notice requesting "suggestions, recommendations and comments on innovative packaging, storage and disposal systems, technologies or designs that could be used to prevent or deter misuse and abuse of opioid analgesics by patients and others." On its own initiative, the agency has extended the original June 9, 2014, comment deadline to August 7.

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The U.S. Patent and Trademark Office **requests** comments from participants on all aspects of the new administrative trial proceedings under the America Invents Act, including the final rules and trial practice guide issued in August and September 2012. The comment deadline is September 16, 2014. Administrative trial proceedings include *inter partes* review, post-grant review, covered business method patents review, and derivation proceedings.

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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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