Shook, Hardy & Bacon L.L.P.

ISSUE 77 | MAY 1, 2014

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

FIRM NEWS

Strand & Underhill to Bring SHB Expertise to IP Litigation Seminar

Shook, Hardy & Bacon Intellectual Property (IP) Partner **Peter Strand**, who chairs DRI's Intellectual Property Litigation Committee, will preside over the first-time attendees breakfast during the organization's May 8-9, 2014, **IP litigation seminar** "The IP Litigator: Protect, Defend, Prevail." He will join conference chairs in opening the program with a welcome and introduction. Also taking part in this continuing legal education program is SHB Global Product Liability Partner **Kevin Underhill**, whose presentation is titled "Lowering the Bar on Ethics."

Kaplan & Woodbury Join Faculty at DRI Drug and Medical Device Seminar

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partners **Harvey Kaplan** and **Marie Woodbury** will participate in DRI's "**Drug and Medical Device Seminar**" slated for May 15-16, 2014, in Washington, D.C. Kaplan will serve as the moderator of a panel of judges discussing "Mass Tort Coordination Between Federal and State Jurisdiction," while Woodbury will serve on a panel demonstrating "Trial Skills: Warnings, Experts, and General Causation."

Garretson to Speak During ACI Biosimilars Summit

Shook, Hardy & Bacon Intellectual Property Prosecution & Counseling Partner **John Garretson** will participate in the American Conference Institute's (ACI's) "**5th Annual Summit on Biosimilars**" in New York City, June 4-6, 2014. Garretson will be part of a panel discussion on "Going Beyond the Hatch Waxman Comparisons: Delving into Pre-Suit Due Diligence and Pre-Litigation Tactics for Evaluating Patent Strength and Assertion Strategies." The firm is a conference co-sponsor.

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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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IP NEWS

Federal Circuit Rules on Zero Damages and Standard-Essential Patents

In a closely watched case, a divided Federal Circuit Court of Appeals panel has determined that U.S. Circuit Judge Richard Posner, presiding as a district judge, erred in certain claim construction and expert-testimony admissibility rulings, and in awarding zero damages for patent infringement and applying a per se rule that injunctions are unavailable for infringed standard-essential patents. ***Apple, Inc. v. Motorola, Inc.*, Nos. 2012-1548, -1549 (Fed. Cir., decided April 25, 2014)**. At issue were claims and counter-claims for infringement relating to patents used to make cell phones.

Chief Judge Randall Rader would have ruled that a genuine issue of material fact existed as to whether Apple was an unwilling licensee whose continued infringement of a standard-essential patent caused irreparable harm and thus summary judgment should not have decided the issue. Judge Sharon Prost objected to the proper construction of the "heuristic" claim terms in one of the patents and further dissented from the majority's decision to vacate the district court's grant of summary judgment as to Apple's request for an injunction.

Concerning the expert testimony excluded by the lower court, the Federal Circuit cautioned trial courts not to weigh facts, evaluate the correctness of conclusions, impose their own preferred methodology, or judge credibility, especially in the context of patent damages. Noting that estimating "reasonable royalty" is not an exact science, the court said that, as long as the proffered testimony is based on reliable principles and methods and the expert is otherwise qualified to render a damages opinion, the trial judge may not properly exclude it.

The court also faulted Judge Posner with excluding expert testimony as incurably biased because it was based on technical advice provided by the company that hired the adviser and the expert. According to the court, Federal Rule of Evidence 703 "does not predicate admissibility on the source of the facts or data or, in particular, on whether the source is employed by either of the parties. . . . While it may be true that the potential for bias is an inherent concern with respect to all hired experts, this concern is addressed by the weight given to the expert's testimony, not its admissibility."

Regarding the lower court's award of zero damages after excluding most of the expert damages testimony, the Federal Circuit stated, "Due to the procedural posture in this case [on summary judgment], we must assume that the patents at issue are valid and infringed. With infringement assumed, the statute requires the court to award damages 'in no event less

than a reasonable royalty. . . . Because no less than a reasonable royalty is required, the fact finder must determine what royalty is supported by the record." In the court's view, "a fact finder may award no damages only when the record supports a zero royalty award." Here, the alleged infringer "has not demonstrated that there is no genuine issue of material fact regarding whether zero is a reasonable royalty for infringement of the '647 patent. . . . In contrast, Apple presented admissible evidence that it is entitled to a non-zero royalty. That Apple's royalty estimate may suffer from factual flaws does not, by itself, support the legal conclusion that zero is a reasonable royalty."

The court rejected the argument of several *amici* that standard-essential patents, which the patent owner has agreed to license on fair, reasonable, and non-discriminatory (FRAND) terms, require a separate rule or analytical framework for addressing injunctions. According to the court, existing case law "provides ample strength and flexibility for addressing the unique aspects of FRAND committed patents and industry standards in general." Ruling that the lower court's per se rule was error, the court stated, "A patentee subject to FRAND commitments may have difficulty establishing irreparable harm. On the other hand, an injunction may be justified where an infringer unilaterally refuses a FRAND royalty or unreasonably delays negotiations to the same effect. . . . To be clear, this does not mean that an alleged infringer's refusal to accept any license offer necessarily justifies issuing an injunction." Applying a flexible approach based on the facts, the court determined that the patent holder here was not entitled to an injunction for infringement of the '898 patent and remanded for further proceedings.

INVESTOR NEWS

Biopharmaceutical Secures $22.5 Million to Advance Nano-Based Eye Disease Therapeutics

Kala Pharmaceuticals, Inc., a Waltham, Massachusetts-based company developing ocular disease treatments, has reportedly raised $22.5 million in a Series B financing tranche from new and existing investors. According to Ysios Capital's General Partner Karen Wagner, who will join Kala's board of directors, "Leveraging its MPP (Mucus Penetrating Particle) nanotechnology, Kala has developed topical eye drops that allow therapeutic agents to pass through the mucus layer of the eye's surface, facilitating penetration into deeper tissues of the eye, including the retina. This approach has yielded game-changing clinical-stage product candidates that may provide more convenient dosing for patients and improve efficacy in a range of ophthalmic indications, including dry eye disease and wet age-related macular degeneration."

Kala Pharmaceuticals will use the financing proceeds to advance the development in clinical trials of its loteprednol etabonate MPP program to treat a range of issues from post-operative inflammation and pain following cataract surgery to diabetic macular edema and retinal vein occlusion. *See Kala Pharmaceuticals, Inc. News Release*, April 23, 2014.

$30 Million Series B Financing to Support Tumor Sequencing Test

After completing a Series B financing round, Guardant Health™ has reportedly secured more than $30 million to support the ongoing commercialization of its GUARDANT360™ non-invasive tumor sequencing test. Located in Redwood City, California, the company has developed a "pan-cancer test that aids oncologists in making more informed, personalized treatment decisions based upon the patient's specific genomic alterations across dozens of genes via a simple blood test."

The test relies on Digital Sequencing™, "a proprietary method of capturing and genetically profiling trace fragments of tumor DNA that are shed into the blood stream and provides high-fidelity tumor sequencing information at the single-molecule level." Apparently, cancer treatments can fail over time because the genetic makeup of many cancers evolves as a response to therapy; the only way to detect these changes to date has been with biopsies. Khosla Ventures founding partner Samir Kaul, who will join Guardant's board of directors, said that the investment company was pleased to partner with Guardant "to help vastly improve cancer care through liquid biopsies." *See PRNewswire*, April 22, 2014.

Cancer Drug Maker Raises $59.5 Million in Oversubscribed Financing Round

ProNAi Therapeutics, Inc., which develops novel nucleic acid therapeutics to treat various genetically defined diseases, including certain cancers, has reportedly closed an oversubscribed $59.5 million Series D funding round. The Plymouth, Michigan-based company's lead drug candidate, PNT2258, targets a specific gene and has apparently shown a systemic anti-tumor effect for patients whose cancers express that gene. According to ProNAi President and CEO Mina Sooch, the company "has overcome the nucleic acid delivery challenges faced by competitive programs by incorporating our unique single stranded, chemically unmodified DNAi® oligonucleotide into a differentiated lipid delivery system. The combination of genetic specificity with effective IV delivery provides us the opportunity to construct potential therapies with a broad range of targets in oncology and other diseases." *See ProNAi Therapeutics, Inc. Press Release*, April 21, 2014.

European Parliament Approves Second Medicines R&D Initiative

With opposition from the Green group, the European Parliament has apparently approved the second Innovative Medicines Initiative (IMI2), a €3 billion research program jointly run by the European Commission and pharmaceutical industry. Spanning 2014-2024, IMI2 will reportedly focus on the development of new drugs that will contribute to lifelong health and wellbeing, expected to gain in importance with an aging population, as well as increasing levels of chronic and degenerative diseases. Trade unions are reportedly concerned about a pharmaceutical industry employment crisis in the midst of large company generation of "mind-boggling" profits from patents. Green representatives suggested that small- and medium-sized entities are vulnerable, because the biggest companies set the research objectives and have an advantage when research funds are distributed. The first IMI initiative reportedly funded 40 projects, developed new therapies for patients and created 1,500 new jobs with a budget of €2 billion. *See EurActiv.com*, April 15, 2014.

Investors Support Gene Therapy Tools for Eye Disease Treatment

New investors led by Venrock and including Deerfield, Adage Capital Management and Redmile Group, among others, have participated in a successful $55 million Series B financing round for Avalanche Biotechnologies, Inc. Headquartered in Menlo Park, California, the company apparently develops innovate gene therapies for serious eye diseases, including wet age-related macular degeneration and other retinal diseases that may lead to vision loss. Proceeds will be used to advance Avanlanche lead product, AVA-101, in clinical programs and further invested in manufacturing and clinical infrastructure, in addition to the acceleration of pipeline program development. Avalanche Board of Directors Chair Mark Blumenkranz said, "Gene therapy has come a long way over the last several years toward realizing its potential as a powerful treatment modality. Avalanche's approach is an elegant solution that addresses this major unmet need." *See Avalanche Biotechnologies, Inc. News Release*, April 22, 2014.

BUSINESS CLIMATE

Drug Prices Not the Same as Drug Costs

Drug discovery scientist Ashutosh Jogalekar has authored a *Scientific American Blog* post that takes issue with sensational news headlines that compare drug manufacturing costs with what appear to be grossly inflated patient prices. Noting that a new hepatitis C drug has rewarded the developer and its shareholders with "handsome profits," Jogalekar

points out that every penny in addition to the manufacturing cost is not part of the profit margin, because the cost of development is not factored into that cost. He observes that drug development involves "very significant barriers . . . in the form of formidable scientific challenges, patent cliffs and FDA [Food and Drug Administration] hurdles." He also contends that the drug's $84,000 price tag is "still lower than what the price of hospitalization and liver transplants would have been."

According to Jogalekar, it takes some $5 billion to develop a new drug. And the high cost of drugs "is not because we are greedy, it's because we are stupid. . . . The complexities of human biology thwart us at every stage and luck plays an inordinately large role in our success. Even basic issues in drug discovery—understanding how drugs get past cell membranes for instance—are generally unsolved problems, and the profligate inefficiency of the process would truly shame us if we knew how to do it better. The path from a new idea in pharmaceutical research to an actual drug is akin to a path trodden by a blind man along the edge of a cliff at night." He concludes, "The scientific challenges in drug discovery are a major reason why drugs are so expensive." *See Scientific American Blog*, April 24, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FDA Issues Draft Guidance on Voluntary Medical Device Approval Program

The U.S. Food and Drug Administration (FDA) has **issued** draft guidance titled "Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions." Comments are requested by July 22, 2014.

FDA's proposed expedited access premarket approval program will, according to a spokesperson, allow "manufacturers to engage early and often with the agency." Anticipating that most devices entering the program will be in the pre-clinical trial phase, FDA expects that the voluntary program, when finalized, "will help patients have more timely access to these medical devices by expediting their development, assessment and review, while preserving the statutory standard of reasonable assurance of safety and effectiveness for premarket approval." The program will apparently feature senior FDA management involvement and a collaboratively developed plan for collecting the scientific and clinical data to support approval. *See FDA Press Release,* April 22, 2014.

Massachusetts Issues Painkiller Restrictions As Ban Expires

The Massachusetts Department of Public Health has **issued** an order that places restrictions on those prescribing hydrocodone-only medications; the order affects Zohydro ER, an opioid Food and Drug Administration

(FDA)-approved painkiller made by Zogenix, Inc., which prevailed in court and obtained a preliminary injunction to stop the commonwealth from enforcing its prohibition on the drug. Details about the litigation and the court's ruling appear in Issue 76 of this *Bulletin*.

Under the order, prescribers must use the prescription monitoring program (PMP) before "prescribing a hydrocodone-only extended release medication that is not in an abuse deterrent formulation." The program requires an evaluation of "a patient's prescription history prior to each instance of issuing a prescription," and, as to Zohydro ER, will require a check of the patient's prescription record every 30 days, while she is prescribed this medication.

Meanwhile the commonwealth's Board of Registration in Medicine has adopted emergency regulations for licensees, who, before prescribing such medication, must (i) conduct a patient risk assessment, "including an evaluation of the patient's risk factors, substance abuse history, presenting conditions, current medications, and PMP data"; (ii) discuss the medication's risks and benefits with the patient; (iii) reach a "pain management treatment agreement" with the patient, including drug screening, pill counts, safe storage and disposal, and provide a letter of medical necessity for the pharmacy filling the prescription; and (iv) include this information in the patient's medical records. *See Massachusetts Department of Health & Human Services News Release*, April 22, 2014.

In a related development, U.S. Sen. Judiciary Chair Patrick Leahy (D-Vt.) and Sen. Richard Blumenthal (D-Conn.) have written to FDA Commissioner Margaret Hamburg requesting that the agency expedite the review of new drug applications for "abuse-deterrent formulations of single-entity hydrocodone products." They note that FDA approved Zohydro ER, despite its lack of abuse-deterrent properties, and state that they "share the concerns of the many governors and state attorneys general who believe this powerful drug is all but certain to exacerbate our nation's addiction to opioid analgesics, which results in tens of thousands of overdose deaths each year." *See Sen. Patrick Leahy News Release*, April 28, 2014.

China's Medical Device Regulations Take Effect June 1

According to news sources, China's amended medical device rules, which increase fines for illegal manufacturing and strengthen government oversight of the industry, take effect on June 1, 2014. The original law capped fines at five times the value of the goods; under the new regulatory regime, the top fine has been raised to 20 times the value of the goods. Among the potential violations are operating without required licenses or misleading regulators. The rules were reportedly overhauled to enhance the safety and effectiveness of medical devices in a market expected to double to $50 billion by 2020. The new rules will require

adverse event monitoring and give local regulators the authority to seize records and devices and even close facilities used for illegal production and distribution. *See Reuters*, March 31, 2014; *Bloomberg BNA Product Safety & Liability Reporter™*, April 11, 2014.

LITIGATION

U.S. Supreme Court Opens Door to Fees in Patent Assertion Entity Litigation

The U.S. Supreme Court has unanimously ruled that the Federal Circuit Court of Appeals erred in reviewing *de novo* a district court "exceptional" case finding under section 285 of the Patent Act, which allows the award of attorney's fees to the prevailing party in patent infringement litigation deemed to be exceptional. ***Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, No. 12-1163 (U.S., decided April 29, 2014)**. According to the Court, "the determination whether a case is 'exceptional' under §285 is a matter of discretion" and is reviewed under a less rigorous abuse-of-discretion standard, rather than *de novo* for decisions on "questions of law." The Court reversed the judgment and remanded for further proceedings.

At issue was a patent owned by Allcare Health Management Systems covering "utilization review" in "managed health care systems." Health insurance company Highmark Inc. filed a declaratory judgment action seeking to have the patent declared invalid and unenforceable and, to the extent it was valid, a declaration that its actions did not infringe the patent. Allcare counterclaimed for patent infringement, and both parties filed motions for summary judgment. The district court entered a final noninfringement judgment, and Highmark filed a motion for fees under section 285.

The court agreed that Allcare had "pursued this suit as part of a bigger plan to identify companies potentially infringing the '105 patent under the guise of an informational survey, and then to force those companies to purchase a license of the '105 patent under threat of litigation." The court also found that Allcare had engaged in a pattern of "vexatious" and "deceitful" conduct throughout the litigation, maintaining its claims against Highmark long after the claims had been shown by its own experts to be without merit. The district court awarded Highmark nearly $4.7 million in attorney's fees, more than $209,000 in expenses and $375,400 in expert fees. If the Federal Circuit finds that the district court did not abuse its discretion, this award will be affirmed.

NEWS BYTES

The U.S. Food and Drug Administration (FDA) **seeks** input "on the design and conduct of the postmarketing requirements (PMRs) for the class-wide extended-release/long-acting (ER/LA) opioid analgesic drug products to

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further assess the serious risks of misuse, abuse, hyperalgesia, addiction, overdose, and death associated with their long-term use." FDA will conduct a public meeting on May 19-20, 2014, in Silver Spring, Maryland, to hear from stakeholders. Those wishing to present during the meeting, must register before May 9; attendees are asked to register by May 12, and comments are requested by June 19. The meeting will be Webcast live; the video will be available online for one year.

The U.S. Food and Drug Administration **announces** a May13-15, 2014, public workshop in Gaithersburg, Maryland, titled "Proposed Strategy and Recommendations for a Risk-Based Framework for Food and Drug Administration Safety and Innovation Act Health Information Technology." The discussion topic will be the Food and Drug Administration Safety and Innovation Act Health Information Technology (IT) report "that contains a proposed strategy and recommendations on an appropriate, risk-based framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication." Online registration will close on May 2; comments are requested by June 12.

The U.S. Patent and Trademark Office (USPTO) **hosts** a May 9, 2014, public forum to consider feedback on its "Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, and Natural Products," which was issued in March. According to USPTO, "[t]he forum will provide an opportunity for participants to present their interpretation of the impact of Supreme Court precedent on the complex legal and technical issues involved in subject matter eligibility analyses during patent examination." Comments may be submitted at any time.

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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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