Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

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IP NEWS

Divided Federal Circuit Rules Claim Construction Is De Novo Review Matter

A split *en banc* Federal Circuit Court of Appeals has declined an invitation to overturn 15-year-old precedent and determined that "appellate review of district court decisions concerning the meaning and scope of patent claims—called 'claim construction'"—will remain de novo, thus requiring no deference on appeal to the district court's interpretation of patent claims. ***Lighting Ballast Control LLC v. Philips Elec. N. Am. Corp.*, No. 2012-1014 (Fed. Cir., decided February 21, 2014)**. So ruling, the court reinstated a panel ruling that applied the correct appellate standard.

The issue generated 21 *amicus curiae* briefs on behalf of 38 entities presenting three general views, which the majority summarized in defending its position that "the court should retain plenary review of claim construction, thereby providing national uniformity, consistency, and finality to the meaning and scope of patent claims. The totality of experience has confirmed that *Cybor* [*Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998),] is an effective implementation of *Markman II* [*Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), (*Markman II*), *aff'g, Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc) (*Markman I*)], and that the criteria for departure from *stare decisis* are not met."

The four dissenting judges called the majority opinion "surprising" and noted, "[c]riticism of and debate over *Cybor* have been widespread since it issued—not only among legal scholars and patent practitioners, but also among members of this court." Focusing on the U.S. Supreme Court's *Markman II* ruling, the dissent states, "construing the claims of a patent at times requires district courts to resolve questions of fact. And, [the majority] puts itself at odds with binding congressional and Supreme Court authority when it refuses to abide by the requirements of Rule 52(a)(6) of the Federal Rules of Civil Procedure, which expressly instructs that, on appeal, *all* "findings of fact . . . must not be set aside unless clearly erroneous."

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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

Medical Device Co. Seeks Crowdfunding to Pay for Field Trials

Newcastle, U.K.-based biotechnology medical device company QuantuMDx has sought investors via crowdfunding on the Internet. Hoping to raise $50,000 for expanded clinical trials of its malaria diagnostic device, the company used campaign trailers on the company's YouTube channel to introduce the public to its technology, described as a handheld laboratory that can complete a sample-to-result malaria DNA test in less than 15 minutes. QuantuMDx reportedly expects to commercialize devices in 2015 that can help treat malaria, TB and HIV by detecting and monitoring emerging drug resistance. As of February 24, 2014, some 93 investors had provided nearly $13,000 to the company via Indiegogo. *See QuantuMDx News Release*, January 9, 2014; *MedCityNews.com*, February 13, 2014.

Fifth Massachusetts Biotech Goes Public in 2014, Raises $84 Million

Clinical stage biopharmaceutical company Concert Pharmaceuticals Inc. has reportedly raised some $84 million in an initial public offering, the fifth by a Massachusetts biotech in 2014. Shares rose 18 cents from the offering price of $14, representing a 1.3 percent gain. The company sold 6 million shares and gave the underwriters a 30-day option to purchase up to an additional 900,000 shares of common stock. Focusing on novel small molecule drugs to treat central nervous system disorders, renal disease, inflammation, and cancer, the Lexington, Massachusetts-based company apparently starts with "approved drugs, advanced clinical candidates or previously studied compounds that have the potential to be improved with deuterium substitution to enhance clinical safety, tolerability and efficacy." *See The Boston Globe*, February 13, 2014; *Concert Pharmaceuticals Inc. Press Release*, February 19, 2014.

Injectible Fat Melting Drug Co. Completes Series C Financing Round

Lithera, Inc., which focuses on aesthetic medicine and ophthalmology, has reportedly completed the final tranche of a Series C funding round, raising an additional $8 million in equity capital for a total of $35.6 million in this round. The San Diego, California-based company plans to use the proceeds primarily to support efforts to advance lead product candidate LIPO-202, described as "a novel, physician-administered, injectable pharmaceutical product designed to produce localized non-ablative reduction of subcutaneous abdominal fat" in non-obese patients. President and CEO George Mahaffey said, "Securing this final tranche of the Series C financing from new and existing investors demonstrated continued confidence in LIPO-202. This funding will help building the robust clinical profile established to date for LIPO-202." *See Lithera, Inc. News Release* February 11, 2014.

GenVec Receives Third Milestone Payment for Hearing and Balance Disorder Treaments

Biopharmaceutical company GenVec, Inc. has reportedly received a $2-million milestone payment, the third in its collaboration with Novartis for the clinical development of CGF166, a novel hearing-loss treatment deemed effective by the U.S. Food and Drug Administration on February 7, 2014. Eligible under its agreement with Novartis for upfront and milestone payments totaling $213.6 million, the Gaithersburg, Maryland-based company develops hearing-loss and balance-disorder treatments from its proprietary gene-delivery technologies. *See GenVec, Inc. Press Release*, February 13, 2014.

Biopharmaceutical Company Receives Parkinson's Funding Grant

The Michael J. Fox Foundation for Parkinson's Research has reportedly provided a grant to Pine Brook, New Jersey-based biopharmaceutical company Ezose Sciences Inc. to apply its Glycan*Map*® technology to the investigation of "the role of sugars known as glycans in Parkinson's disease." According to the company, "[g]lycans could serve as novel biomarkers for guiding clinical management and drug development and provide insight into disease mechanism and novel drug targets." Glycan chains apparently attach to many proteins expressed by cells in the body and affect their biochemical function. The speed, scope and quantitative power of Ezose's technology could apparently help discover "novel glycan changes associated with altered protein function during the onset and progression of wide-ranging diseases, including Parkinson's disease and other neurological disorders."

A foundation spokesperson said, "Two important steps toward the development of a disease-modifying therapy for Parkinson's are greater understanding of the underlying pathology of the disease and validation of a reliable biomarker. Ezose's glycan analysis offers a new approach to serve those goals and bring us closer to a Parkinson's cure." *See Ezose Scinces Inc. News Release*, February 19, 2014.

BUSINESS CLIMATE

Life Sciences Investments Slow in 2013 Overall, Show Vigor in Q4

According to PricewaterhouseCoopers (PwC) latest MoneyTree™ Report, venture capital funding for the life sciences sector, including biotechnology and medical devices, fell by 1 percent in dollars invested and 3 percent in the number of deals in 2013, compared to 2012 activity. Year-end numbers, however, were more encouraging, with life sciences investments rising to $1.8 billion in the final quarter of the year (Q4), up 19 percent from the

$1.5 billion invested during the previous quarter. The industry's share of total venture capital funding fell, however, from 25 percent in 2012 to 23 percent in 2013.

PwC Life Sciences Partner Greg Vlahos said, "The fourth quarter and 2013 year-end numbers show there is continued interest in Biotechnology even as Medical Devices slowed down during the year. With the strong exit markets for biotechnology in 2013, 2014 is set up for renewed interest in life sciences. The enduring interest in early-stage opportunities will continue to drive investments in the sector."

Titled "Medtech Slowdown," the PwC February 2014 report also notes that the top five metropolitan regions that received the most life sciences venture capital during Q4 2013 were "San Francisco Bay ($550 million), Boston ($382 million), Seattle ($186 million), San Diego Metro ($95 million), and New York Metro ($83 million)."

Thomson Reuters Sponsors Life Sciences Dealmaking Forum

Thomson Reuters will **convene** its 18th annual "Allicense 2014: The Next Generation in Dealmaking" in San Francisco, California, April 29-30, 2014. Business developers, dealmakers and top executives in the life sciences industry will participate in this forum, which brings together key players in the pharmaceutical, biotechnology and financial sectors to address relevant issues, share experience with innovative deals and structures and discuss issues facing the industry.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Hearing on OTC Drug Review Scheduled

The U.S. Food and Drug Administration (FDA) will **conduct** a public hearing on March 25-26, 2014, in Silver Spring, Maryland, "to obtain information and comments from the public on the strengths and weaknesses of the current OTC [over-the-counter] Monograph Process, and to obtain and discuss ideas about modifications or alternatives to this process." Those wishing to attend or provide oral testimony must register by March 12, and comments are requested by May 12.

FDA's OTC Monograph Process encompasses the agency's review of nonprescription drugs marketed under its OTC drug review procedures, 21 C.F.R. part 330, in effect since 1974. While the 40-year-old process, in FDA's view, has been successful in maintaining the safety and efficacy of thousands of OTC drug products by therapeutic category, certain challenges remain, including (i) "[t]he large number of products marketed under the OTC Drug Review for which there are not yet final monographs"; (ii) "limitations on FDA's ability to require, for example, new warnings or other labeling changes to address

emerging safety or effectiveness issues for products marketed under the OTC Drug Review in a timely and effective manner"; and (iii) "the inability of the OTC Drug Review to easily accommodate innovative changes to products regulated under the OTC Drug Review." As part of this initiative, FDA is interested in ideas to change the OTC monograph process "or ideas for its replacement with an entirely new regulatory or statutory framework."

Shook, Hardy & Bacon Regulatory Practice Co-Chair **Debra Dunne**, who participated in the Food & Drug Law Institute's (FDLI's) "Introduction to Drug Law & Regulation: The Legal Framework for Drug Regulation" held in November 2013, discussed **OTC oversight issues** during her presentation "Over-the-Counter (OTC) Drug Products." She and SHB Pharmaceutical & Medical Device Litigation Practice Associate **Brian Guthrie** have authored an article titled "Crafting Changes for the Future: Increasing the Availability of Nonprescription Drugs" that will appear in the March/April 2014 issue of FDLI's *Update* magazine.

FDA Launches Secure Supply Chain Pilot Program

The U.S. Food and Drug Administration (FDA) has **announced** that 13 pharmaceutical companies have qualified to participate in its two-year pilot program to improve the security of imported drugs. The companies "will receive expedited entry for the importation of up to five selected drug products into the United States." According to the agency, the program's goal "is to enable the FDA to evaluate resource savings that will allow the agency to focus imports surveillance resources on preventing the entry of high-risk drugs that are the most likely to compromise the quality and safety of the U.S. drug supply." Limited to 100 qualified applicants, the program will be evaluated for effectiveness "at enhancing imported drug compliance with FDA regulations and the security of the drug supply chain." If it succeeds, the agency could establish a more permanent program with participation extended to additional companies.

The participating companies have apparently met a number of conditions, including promising to comply with U.S. drug safety laws, having a "validated secure supply chain protocol per the U.S. Customs and Border Protection's Customs-Trade Partnership Against Terrorism (C-TPAT) program," having effective recall and corrective action plans, and "maintaining control over their drugs from the time of manufacture abroad through entry into the United States." *See FDA News Release*, February 18, 2014.

USPTO Deputy Director Discusses Executive Actions to Improve Patent System

U.S. Patent and Trademark Office (USPTO) Deputy Director Michelle Lee has **reported** the initiatives that the office has already undertaken or will undertake to support the president's intention to improve the patent system

through executive action. Among them are a new rulemaking requiring patent applicants to provide patent ownership information that will be made publicly available, the implementation of training for patent examiners to address overly broad patents and increase patent clarity, a "new online toolkit" to help those who receive a patent infringement letter, and expanded public outreach efforts and increased empirical research examining "the interaction of various aspects of our patent system [to] provide insights on how to further reduce unnecessary litigation and improve the quality of patents." *See Director's Forum: A Blog from USPTO's Leadership*, February 20, 2014.

LITIGATION

U.S. Supreme Court Considers Attorney's Fees in Patent Litigation

The U.S. Supreme Court has heard oral argument in two cases presenting issues relating to the standards that trial and appellate courts apply when awarding attorney's fees in certain patent cases. *Octane Fitness v. Icon Health & Fitness*, No. 12-1184 (U.S., argued February 26, 2014) ("Whether the Federal Circuit's promulgation of a rigid and exclusive two-part test for determining whether a case is 'exceptional' under 35 U.S.C. § 285 improperly appropriates a district court's discretionary authority to award attorney fees to prevailing accused infringers in contravention of statutory intent and this Court's precedent, thereby raising the standard for accused infringers (but not patentees) to recoup fees and encouraging patent plaintiffs to bring spurious patent cases to cause competitive harm or coerce unwarranted settlements from defendants."); and *Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, No. 12-1163 (U.S., argued February 26, 2014) ("Whether a district court's exceptional-case finding under 35 U.S.C. § 285 (which permits the court to award attorney's fees in exceptional cases), based on its judgment that a suit is objectively baseless, is entitled to deference."). Decisions are expected by the end of the Court's term in June 2014.

NEWS BYTES

The U.S. Food and Drug Administration **requests** comments on the estimated time burdens of a proposed study that "will investigate the impact of limiting the risks presented in DTC [direct-to-consumer] prescription drug television ads to those that are serious and actionable, and including a disclosure to alert consumers that there are other product risks not disclosed in the ads." According to the agency, concerns have arisen over whether the "major statement" included in current TV ads is "too long, which may result in reduced consumer comprehension, minimization of important risk information and, potentially, therapeutic noncompliance due to fear of side effects." Comments are requested by April 21, 2014.

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The U.S. Food and Drug Administration **reports** on "the status of post-marketing requirements and commitments required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct."

The U.S. International Trade Administration **issues** a request for nominations to 16 Industry Trade Advisory Committees (ITACs) for which it has renewed the charters until February 2018. Among those committees with vacancies are ITAC 3, Chemicals, Pharmaceuticals, Health/Science Products and Services; ITAC 15, Intellectual Property Rights and ITAC 16 Standards and Technical Trade Barriers. Applicants must be U.S. citizens and must not be federally registered lobbyists. Meetings occur in Washington, D.C., some six times each year. Nominations will be accepted through February 14, 2018.

The U.S. Patent and Trademark Office **extends** the comment deadline and schedules two public hearings—March 13 and 26, 2014, in Alexandria, Virginia, and San Francisco, California, respectively—on a notice of proposed rulemaking (NPR) that would change the rules of practice to "require that the attributable owner, including the ultimate parent entity, be identified during the pendency of a patent application and at specified times during the life of a patent. The Office is specifically proposing that the attributable owner be identified on filing of an application (or shortly thereafter), when there is a change in the attributable owner during the pendency of an application, at the time of issue fee and maintenance fee payments, and when a patent is involved in supplemental examination, *ex parte* reexamination, or a trial proceeding before the Patent Trial and Appeal Board." Comments are now requested by April 24, 2014.

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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.

SHB is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most challenging national and international product liability and mass tort litigations.