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

Federal Court Enjoins Nebraska AG from Enforcing Cease and Desist Order in Patent-Infringement Litigation

Finding that a Nebraska attorney general (AG) order directing counsel for a purported non-practicing entity (NPE) to cease threatening state businesses with patent-infringement litigation likely violates the NPE's First Amendment and due process rights, a federal court has issued a preliminary injunction forbidding the AG from enforcing the July 2013 cease and desist order. ***Activision TV, Inc. v. Pinnacle Bancorp, Inc.*, No. 13-215 (U.S. Dist. Ct., D. Neb., order entered September 30, 2013)**.

According to the court, patent owner Activision TV has "suffered injury, and continues to suffer injury, as a result of the cease and desist order," which prohibited its law firm "from initiating new patent infringement enforcement efforts" in the state while the AG investigated whether the firm's activities violated state consumer-protection law. Deeming the cease and desist order akin to a prior restraint, the court was "deeply concerned about the ability of the Attorney General to issue cease and desist orders, prior to the conclusion of the investigation, prior to any negative findings, prior to any hearings, and prior to permitting submission of documents and evidence" by the law firm. Because the company has a constitutional right to associate with counsel of its choosing without interference from the state, the court ruled that the inability of the law firm to submit letters to businesses in Nebraska "clearly infringes on the First Amendment rights of Activision to be represented by counsel of their [sic] choice." Because federal law preempts state action in "the area of patent law," the court further determined that "[a]llowing the attorney general to interfere might be harmful to the patent process." The court also noted that the company had a "due process right to a meaningful process prior to issuance of a cease and desist order."

The court had previously entered a limited injunction to stop enforcement of the cease and desist order as to this case and future federal court cases after finding that the AG intended that the order apply only to the

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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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law firm's issuance of letters to potential new infringers. Activision TV has filed more than two-dozen patent-infringement lawsuits throughout the United States in 2013. The patents at issue involve remote-control electronic-display systems used in many retail establishments.

INVESTOR NEWS

Cancer Diagnostics Firm Seeks $46 Million in Stock Offering

Rutherford, New Jersey-based Cancer Genetics, Inc. (CGI) has filed a registration statement with the U.S. Securities and Exchange Commission indicating its intent to raise up to $46 million in a public stock offering. CGI offers cancer diagnostic products and services and treatments that are tailored to individual genetic profiles. The company reportedly made a public offering of $15 million of its shares and began trading on the NASDAQ in August 2013. Aegis is listed as the book-running agent. *See genomeweb.com,* October 9, 2013.

Oxford Nanopore Raises $63.7 Million to Advance Sensing Technologies

Oxford Nanopore Technologies Ltd., an Oxford, England-based technology company that develops nanopore-based electronic molecular analysis systems, announced that it has raised $63.7 million from new and existing investors in the United States and Europe. The funds will apparently be used to develop the company's commercial and manufacturing infrastructure, continue research and development in nanopore sensing and for other business purposes, including protecting intellectual property. Oxford Nanopore has reportedly developed a generation of handheld and desktop devices that use a technique known as strand sequencing, in which a string of DNA is guided by an enzyme and passes intact through a tiny hole in a cell membrane one-billionth of a meter wide. According to the company, the devices may be used in scientific research, personalized medicine, crop science, security and defense, and environmental applications. *See Oxford Nanopore Technologies Ltd. News Release,* October 9, 2013.

Biotech with Rare Disease Focus Files for $86 Million IPO

GlycoMimetics, Inc. has reportedly filed a registration statement with the U.S. Securities and Exchange Commission indicating its intent to raise up to $86 million in an initial public offering (IPO). The Gaithersburg, Maryland-based biotech, which develops treatments for orphan diseases—those affecting fewer than 200,000 patients—is reportedly in mid-stage trials of its GMI-1070 treatment for vaso-occlusive crisis, a complication of sickle cell disease. *See GlycoMimetics, Inc. News Release* and *FierceBiotech.com,* October 7, 2013.

Biotech Raises $18.5 Million to Complete NDA for Autism Drug

Curemark LLC has reportedly raised $18.5 million in common equity financing that the company intends to use to complete its new drug application (NDA) for the autism treatment CM-AT and to develop other therapies in its pipeline. "The completion of our latest financing allows us to determine the commercial pathway for CM-AT to bring it to the children who desperately need it," said Founder and CEO Joan Fallon. "In addition, the financing exhibits our investors' continued confidence in the company and will enhance our development pipeline for Schizophrenia, ADHD and Parkinson's [Disease]."

The Rye, New York-based drug research and development company previously announced the successful completion of its Phase III multicenter clinical trial of CM-AT for autism, and the drug met both primary and secondary endpoints in its double-blind, randomized placebo-controlled study of 3- to 8-year-old children with autism. The U.S. Food and Drug Administration reportedly designated CM-AT a "Fast Track" drug in 2010. *See PRNewswire* and *medcitynews.com,* October 8, 2013.

BUSINESS CLIMATE

Hundreds of Rare Disease Treatments in U.S. Development Pipeline

A new **report** from the Pharmaceutical Researchers and Manufacturers of America (PhRMA) claims that 452 medicines and vaccines to address rare diseases are currently in development in the United States. Rare diseases, those affecting fewer than 200,000 patients, affect one in 10 Americans, or a total of 30 million individuals. According to PhRMA, 80 percent of these 7,000 different types of rare diseases and disorders are genetically based, and they include cancer, infectious diseases and neurological disorders. The report credits the Orphan Drug Act of 1983, which provided incentives to companies developing rare disease treatments, with accelerating the rate at which these therapies have been developed and approved. "As of September 15, 2013, the [Food and Drug Administration] has granted the orphan drug designation to 2,899 potential therapies," said PhRMA.

Biotech IPO Market, Booming or Bubbling?

Speakers at a recent Biotechnology Industry Organization (BIO) Investor Forum in San Francisco reportedly claimed that this year's successes for biotech companies in the initial public offering (IPO) market represent a "boom" rather than a "bubble" and could be sustained in the long term. BIO Director of Industry Research and Programs Dave Thomas said that the market is now "getting back to where it should be" after several

disappointing years and undervaluations. Others echoed his sentiment, noting that cash is flowing into global equity markets, contributing to a strong demand for growth sector IPOs in 2013. A spokesperson for Bay City Capital noted that the pharmaceutical industry is flush with cash and looking to acquire biotechs to spur their own growth. *See Reuters*, October 8, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Nobel Prize Winners Decry NIH Spending Cuts

During a recent press conference, the three U.S.-based winners of the 2013 Nobel medicine prize discussed their concern that the government-funded research leading to their discoveries on human cell transport systems might not have been possible in today's sequestration and budget-cutting environment. According to a news source, all three scientists, Randy Schekman, Thomas Suedhof and James Rothman, have received grants from the National Institutes of Health (NIH) during their careers to conduct basic research. They suggested that NIH funding for basic research "made America the great engine of biomedical discovery" and contributed to the growth of the nation's biotechnology and pharmaceutical industries. That funding has apparently fallen significantly, and what remains is increasingly focused on research that can readily be translated into medical applications.

Schekman began his prize-winning research by studying baker's yeast, an effort he said he would not have begun without NIH funding. Contending that "federal paralysis is frankly imperiling our biomedical enterprise," Schekman said, "[m]any of my colleagues, particularly young colleagues, feel they have to work on medically relevant things. For example, yeast, which I continue to view as a valuable model organism, is less popular now because people feel they can't get NIH funding to work on yeast." NIH reportedly spends 80 percent of its budget on more than 300,000 research personnel at more than 2,500 universities and research institutions. *See Reuters*, October 7, 2013.

Final FDA Biosimilar Guidance Expected Within a Year

Without saying what effect the partial government shutdown could have on the agency's agenda, U.S. Food and Drug Administration (FDA) personnel reportedly indicated during a regulatory conference in Boston that the draft biosimilar guidances issued in February 2012 were nearing completion and could be finalized within the next year. According to a news source, FDA Senior Staff Fellow Sue Lim reported that labels for

biosimilars will, for the most part, be the same as those for branded biologics, with some differences to distinguish the drugs. Lim also said that a particular challenge has been the science of highly complex biologic drugs, with the agency focusing study on the relationship between protein attributes and effects on clinical effectiveness and safety. Her remarks were made during the Regulatory Affairs Professional Society's "2013 RAPS: The Regulatory Convergence" conference. *See Law360*, October 2, 2013.

FDA Warns Japan-Based Medical Equipment Maker on Quality Controls

The U.S. Food and Drug Administration (FDA) recently issued a warning letter to a Japan-based company that makes Class I and II non-sterile laser devices used for eye surgery. According to the letter, a May 2013 inspection of Nidek Co. Ltd.'s Aichi facility led to a finding that its devices are "adulterated . . . in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements" of 21 C.F.R. Part 820. Among the other purported violations is an apparent inadequate final inspection procedure that "allows the technician performing the final inspections to decide whether or not to perform some of the final inspection tests. . . . The procedure does not require the technician performing the final inspection to indicate whether the results were copied or actually performed by the technician at the final inspection."

California Governor Nixes Biotech Drug Bill, Approves Compounding Pharmacy Oversight

California Governor Jerry Brown (D) has vetoed a bill (**S.B. 598**) that would have imposed certain requirements on pharmacists substituting a biosimilar product for a branded reference drug. In his veto statement, Brown expressed his concern that because the U.S. Food and Drug Administration has not yet established the "interchangeability" standards for biosimilars, it would be "premature" to require pharmacists to notify prescribing physicians that they have dispensed a biosimilar to fill a prescription. He referred to the controversy that this requirement had engendered among stakeholders, stating "[d]octors with whom I have spoken would welcome this information," but "other large purchasers warn that the requirement itself would cast doubt on the safety and desirability of more cost-effective alternatives to biologics."

Meanwhile, Brown has approved a bill (**S.B. 294**) that would increase state oversight of compounding pharmacies by prohibiting any pharmacy, including those outside the state, from dispensing compounded pharmaceuticals to state residents without first obtaining a "sterile compounding

pharmacy license" from the California State Board of Pharmacy. The law requires the board to adopt "standards for compounding injectable sterile drug products in a pharmacy." The law will take effect in July 2014.

LITIGATION

Federal Circuit Upholds Inequitable Conduct Ruling; Patent Unenforceable

The Federal Circuit Court of Appeals has determined that a district court did not err in finding that the inequitable conduct of the inventor of technology involving wireless transmission of caller identification information rendered certain patents relating to that invention unenforceable. ***Intellect Wireless, Inc. v. HTC Corp.*, No. 2012-1658 (Fed. Cir., decided October 9, 2013)**. The inventor apparently submitted to the U.S. Patent and Trademark Office (USPTO) a declaration under 37 C.F.R. § 1.131 containing false statements—that is, to overcome a prior art reference during prosecution, the inventor asserted that "the claimed invention was actually reduced to practice and was demonstrated at a meeting . . . in July of 1993." The claimed subject matter, however, was never actually reduced to practice. Rather, the device demonstrated in July 1993 was a simulation that "only contained preloaded images for the purpose of demonstration." It was "not capable of wireless communication."

Thus, the court determined that "the district court did not clearly err in concluding that [the alleged infringer] proved materiality by establishing that [the inventor] engaged in affirmative egregious misconduct when he filed a false declaration." The court further agreed with the district court and the alleged infringer that the inventor failed to correct the misrepresentation in a revised declaration and subsequent statements. According to the court, the revised declaration "did not cure the misconduct because it never expressly negated the false references to actual reduction to practice in the original declaration." The court also found support for the district court's determination that the inventor acted with specific intent to deceive USPTO, ruling that he engaged in a pattern of deceit by submitting repeated false affidavits in connection with several related patents.

NEWS BYTES

The U.S. Patent and Trademark Office (USPTO) **seeks** comments under the Paperwork Reduction Act on the revision of a continuing information collection relating to applications for patents. The Office of Management and Budget approved the collection on January 8, 2011, but its notice of action included terms of clearance requiring USPTO to conduct stakeholder outreach as to the burden of 0651–0032 Initial Patent Applications and ways to potentially reduce it before the next collection renewal.

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The *Federal Register* notice includes estimates of the time and expense burdens of completing and filing nearly 70 forms. Comments and recommendations are requested by December 2, 2013.

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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