Shook, Hardy & Bacon L.L.P.

ISSUE 57 | MAY 16, 2013

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Federal Circuit Issues Seven Opinions on Patentability of Software Innovations

The en banc Federal Circuit Court of Appeals has divided over whether method and computer-readable media claims and system claims are directed to eligible subject matter under 35 U.S.C. § 101; the 10 judges who participated authored seven separate opinions. ***CLS Bank Int'l & CLS Servs., Ltd. v. Alice Corp. Pty. Ltd.*, No. 2011-1301 (Fed. Cir., decided May 10, 2013)**. The district court determined that none of the asserted claims was patentable.

While a Federal Circuit majority affirmed the district court's ruling as to the asserted method and computer-readable media claims—albeit for different reasons—the court's equal division over the lower court's ruling on the asserted system claims affirmed its determination on that issue. As a result, the alleged patent infringer will continue to operate a computerized trading platform without making patent-related payments to the patent holder.

According to Chief Judge Randall Rader, "No portion of any opinion issued today other than our Per Curiam Judgment garners a majority. The court is evenly split on the patent eligibility of the system claims. Although a majority of the judges on the court agree that the method claims do not recite patent eligible subject matter, no majority of those judges agrees as to the legal rationale for that conclusion. Accordingly, though much is published today discussing the proper approach to the patent eligibility inquiry, nothing said today beyond our judgment has the weight of precedent."

JOINT VENTURES

Canada to Invest in Plant to Convert Oil Sand GHGs into Biofuels, Other Products

The Government of Canada has reportedly formed a joint venture through the National Research Council of Canada with Canadian Natural Resources Ltd. and Pond Biofuels to build a $19-million Alberta-based plant that will use algae to convert greenhouse gas (GHG) emissions from an oil sands facility into bio fuel. Carbon dioxide from Canadian Natural's Primrose South oil sands

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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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site will reportedly be used to grow algal biomass for further processing into bio fuels, livestock feed and fertilizer. The three-year project is intended to test the technology's viability and feasibility on a large scale. "If proven successful," according to a May 10, 2013, government news release, "it can then be used as a model for recycling industrial emissions in the oil sands, and in industries across Canada and around the world."

INVESTOR NEWS

Biotech Receives $32.5 Million for Cancer Research

Celator Pharmaceuticals, Inc., a Princeton, New Jersey-based company that develops cancer therapies, has raised $32.5 million in the final closing of a private placement of common stock and warrants to purchase common stock. The biopharmaceutical reports that the funds will be used to support a Phase 3 clinical study of its CPX-351 Liposome Injection, an "experimental therapy for secondary acute myeloid leukemia."

According to Celator, the Phase 3 clinical study is designed as a "300-patient, randomized, controlled study comparing CPX-351 to conventional cytarabine and daunorubicin therapy (7+3) with a primary endpoint of overall survival."

Valence Life Sciences, LLC led the financing, which totaled $39.3 million, including an additional $6.8 million from previous closings. Scott Morenstein, Valence Life Sciences Managing Director, will join Celator's board of directors. *See Celator Pharmaceuticals, Inc. News Release,* April 30, 2013.

Molecular Diagnostics Company Expects $13.2 Million in Equity Financing

Vermillion, Inc. has reportedly entered an equity investment deal with some of its investors that will, subject to closing conditions, bring in an initial investment of $13.2 million from the sale of 8.0 million shares of common stock. An additional $18.3 million could be raised, before transactions costs, if the 12.5 million warrants issued to investors as part of the deal are exercised. The Austin, Texas-based company focuses on developing molecular diagnostics for gynecologic cancers and women's health. The proceeds from this transaction will apparently be used "to increase test sales and improve reimbursement for OVA1, expand the commercial opportunity into new markets and advance one or more next-generation ovarian cancer diagnostic tests." *See Vermillion, Inc. News Release*, May 9, 2013.

Natera Secures $54.6 Million Financing to Roll Out Prenatal Test

San Carlos, California-based genetic testing company Natera, Inc. has completed a $54.6-million Series E financing round to support the expansion and rollout of its "non-invasive prenatal test, Panorama™," which can evidently

detect prenatal risk factors for Patau syndrome, Edwards syndrome and Down syndrome with a purported 99-percent accuracy. The financing was led by OrbiMed Advisors, LLC, and Harmony Partners.

"This new financing will support the expansion of our lab and our team to meet the rapidly increasing demand," said Natera CEO Matthew Rabinowitz. "We are fortunate to have a world class investor syndicate that shares our excitement for the technology's potential and look forward to helping expecting families worldwide with Panorama while evaluating these potential expansion opportunities."

Among other things, Natera reports that the test (i) has demonstrated a specificity of 100 percent with no false positives for all of the syndromes tested, (ii) uses fetal cell-free DNA from maternal blood, and (iii) can be used as early as nine weeks' gestation. *See Natera, Inc. News Release,* May 1, 2013.

STAT-Diagostica Secures $22.1 Million in Financing for Near Patient Testing Systems

According to news sources, Barcelona-based STAT-Diagnostica has raised $22.1 million in a Series B financing round that the company will use to (i) complete development of its in-vitro diagnostic system that consolidates molecular and immunoassay techniques in a single device, and (ii) clinically validate its first products. Clinical applications will focus on infectious disease detection, antibiotic-resistance determination and the detection of biomarkers in critically ill patients.

"The Series B financing is a significant milestone that will support our preparation for a European market launch in 2015," said CEO and co-founder Jordi Carrera. "Our ability to close the round is proof of the outstanding team behind the company, and demonstrates the potential of our technology in the fast growing decentralized diagnostics market." Led by new investor Kurma Life Sciences Partners, the financing round drew participation from new investors Idinvest and Caixa Capital Risc, as well as existing investors. *See STAT-Diagnostica Press Release* and *BusinessWire.com,* May 6, 2013.

BUSINESS CLIMATE

NASDAQ Biotechnology Index Surpasses All-Time High in 1Q13

The NASDAQ Biotechnology Index reportedly rose in the first quarter of 2013 (1Q13) above levels last seen during the 2000 genomics bubble peak—the BioCentury 100 and NASDAQ Biotechnology indices increased 16-17 percent in the last quarter, while the Dow and S&P 500 were up just 10-11 percent. Still, the biotech industry raised less through initial public offerings and venture capital in 1Q13 when compared with the same period in 2012. In

conjunction with a strong stock market performance, the biotech industry also saw job postings increase dramatically. In 1Q13, the top 25 companies posted 90 percent more jobs on Monster, 92 percent more on LinkedIn and 29 percent more on Naturejobs when compared with the previous quarter.

Still, while 2012 was a good year for funding the biotech sector as a whole, the private financing available to new, innovative, therapeutic companies has apparently continued a decline that began in 2006. University technology transfer is reportedly spinning out more startups than ever, but, according to *Nature Biotechnology* Business Editor Brady Huggett, "the lack of available capital to sustain fledgling companies does not augur well for the health of the innovative private biotech sector."

Huggett suggests that investing is likely to increase this year given the available funds and because stocks performed well last year, but he believes that certain strategies could successfully address the disappearance of venture-capital funding for biotech startups. These include (i) universities focusing more on developing their own capabilities for validating discovery assets "and getting them to the stage where they are attractive licensing options for the biotech and pharma industry"; (ii) public biotechs becoming "acquirers themselves, and in this way, the pool of purchasers would increase"; and (iii) new sources of capital, such as venture philanthropists and patient groups, supplementing venture-capital funds. *See Nature Biotechnology*, May 2013.

Rapid Biosimilar Growth Seen Through 2023

British market-research firm Visiongain has forecast a $2.445-billion global market for biosimilars in 2013, a 20-percent increase over 2012, with the fastest growth anticipated in biosimilar monoclonal antibodies and insulins. Biosimilars account for just 2 percent of the overall market for biologics, but the market is evidently expected to grow rapidly in the United States and Europe during the next 10 years as biosimilars currently under development are approved. According to Visiongain pharmaceutical market analyst Richard Lang, "Many companies are interested in entering the biosimilars market. These drugs offer a simpler way to launch biopharmaceuticals, compared with developing novel biologics." *See drugstorenews.com*, May 7, 2013.

Universities Abroad Experiment with No-Fee Licensing to Drive Biotech Partnerships

Universities in Australia, Canada, Europe, and the United Kingdom have reportedly embraced a 2010 Glasgow University initiative under which companies interested in partnerships with the institutions gain automatic ownership of intellectual property subject to the collaborations. In return, the companies generally take responsibility for filing and maintaining the patents and sharing royalties after a patent starts generating revenue. The partner-

ships aim to ease access to a university's research expertise to stimulate innovation. Most of the no-fee licenses granted involve small- and medium-sized companies.

Meanwhile, according to an analysis of 387 public-private partnerships that were active in 2012, including research institutes, major areas of interest include cancer, infectious diseases and diagnostics/pharmacogenetics. Harvard University and the University of Texas system reportedly lead the list of universities with the most industry deals; and Cambridge, U.K.-based Horizon Discovery, which focuses on gene-editing, closed five academic deals during the year, more than several large pharmaceutical companies. *See Nature Biotechnology*, May 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Congress Advances Pharma Supply Chain and Animal-Drug User-Fee Laws

The House Energy and Commerce Subcommittee on Health has reportedly approved draft legislation that would change the existing lot-level prescription-drug-tracking system to a unit-level system. The proposal would require various entities along the pharmaceutical supply chain, including manufacturers and wholesale manufacturers, to submit information. The subcommittee also apparently approved a bill (**H.R. 1407**) that would renew the user fees that support the Food and Drug Administration's approval of brand-name and generic drugs for animals.

Meanwhile, the U.S. Senate passed a measure (**S. 622**) by unanimous consent that would also extend the animal-drug user-fee system, which will otherwise expire on October 1, 2013. *See U.S. House Energy & Commerce Committee News Release*, May 8, 2013; *CQ Weekly*, May 13, 2013.

EU Medicines Agency Plans to Appeal Interim Rulings on Release of Clinical Trial Data

According to a news source, European Medicines Agency (EMA) Director Guido Rasi intends to appeal interim rulings recently issued by the European Union's (EU's) General Court to stop the agency from releasing to third parties information on AbbVie and InterMune's clinical trials. ***AbbVie, Inc. v. EMA*, Case T-44/13 (Gen. Ct., decided April 25, 2013)**; ***InterMune UK Ltd. v. EMA*, Case T-73/13 R (Gen. Ct., decided April 25, 2013)**.

The court refused to decide, as a matter of first impression, whether EMA's new disclosure policy infringes the drug makers' right to professional secrecy, noting that it "requires an in-depth examination in the context of the main proceedings," but upheld the applications for interim measures because the drug companies had made a prima facie case.

Rasi claims that transparency is critical to combat a growing level of public distrust of the pharmaceutical industry. Since the end of 2010, EMA has apparently released nearly 2 million pages of detailed clinical trial information in response to requests. AbbVie and InterMune reportedly resisted a request for their data because competitors were evidently among those seeking it. They contend that commercially confidential information in their EMA filings would benefit competitors. *See Reuters*, April 30, 2013.

LITIGATION

SCOTUS Unanimously Rules GM Soybean Patent Infringed

The U.S. Supreme Court has determined that the "exhaustion doctrine" does not apply in the context of a patented genetically modified (GM) seed, and thus a farmer who reproduced patented seeds through planting and harvesting without the patent holder's permission impermissibly infringed the patent. ***Bowman v. Monsanto*, No. 11-796 (U.S., decided May 13, 2013)**. Details about the case, including oral argument before the Court appear in issues **22** and **51** of this *Bulletin*.

Writing for the Court, Justice Elena Kagan stated, "Under the doctrine of patent exhaustion, the authorized sale of a patented article gives the purchaser, or any subsequent owner, a right to use or resell that article. Such a sale, however, does not allow the purchaser to make new copies of the patented invention." According to the Court, this is, in effect, what the farmer did by buying from a grain elevator "commodity soybeans" intended for human or animal consumption, planting them in his fields and then saving seed from those crops to use repeatedly, "until he had harvested eight crops that way."

While the Court recognized the farmer's right to purchase the commodity soybeans, resell them, consume them, or feed them to his animals, it held that the exhaustion doctrine "does not enable Bowman to make *additional* patented soybeans without Monsanto's permission (either express or implied). . . . Because Bowman thus reproduced Monsanto's patented invention, the exhaustion doctrine does not protect him. Were the matter otherwise, Monsanto's patent would provide scant benefit."

Putative Class Alleges Pharma Statements About New Drug Violated Securities Laws

Aveo Pharmaceuticals, Inc. and several of its executives have been targeted in a securities class action filed in a federal court in Massachusetts; named plaintiff Paul Sanders alleges that he and others purchased Aveo securities between January 3, 2012, and May 1, 2013, relying on misleading company statements about the progress of its kidney cancer drug through clinical trials.

Sanders v. Aveo Pharms., Inc., No. 13-11157 (U.S. Dist. Ct., D. Mass., filed May 9, 2013). Ultimately, the Food and Drug Administration's (FDA's) Oncologic Drugs Advisory Committee voted not to recommend approval of tivozanib, allegedly because "the application for investigational agent tivozanib did not demonstrate a favorable benefit-to-risk evaluation for the treatment of advanced renal cell carcinoma (RCC) in an adequate and well-controlled trial."

The complaint details how company statements were purportedly misleading for failing to disclose that FDA had recommended to the company that it conduct an additional phase 3 trial and for making untrue statements about the product's overall safety and efficacy. The plaintiff contends that the statutory safe harbor for forward-looking statements "does not apply to any of the allegedly false statements pleaded," because they were not identified as forward-looking statements when made and lacked meaningful cautionary statements. The plaintiff also claims, in the alternative, that even if the safe harbor does apply to any forward-looking statements, the defendants are liable because they knew the statements were false.

Seeking to certify a class of all who purchased Aveo securities during the relevant time period, the plaintiff alleges violations of sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5. He seeks damages, interest, attorney's fees, and costs.

NEWS BYTES

The National Institutes of Health (NIH) Office of Biotechnology Activities **proposes** revising the "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" "to streamline review of certain human gene transfer trials that present a low biosafety risk." The types of trials that may qualify for an exemption from further institutional biosafety committee review include those involving gene transfer products either frequently used over a number of years or of sufficient low biosafety risk. Comments are requested by June 12, 2013.

The Office of U.S. Trade Representative **issues** a "Special 301" Report that highlights concerns about the recent decision by India's Supreme Court "with respect to India's prohibition on patents for certain chemical forms absent a showing of 'enhanced efficacy,'" which apparently earned India a place on the U.S. "priority watch list," characterized in the media as a "special trade blacklist." According to the report, "the decision appears to confirm that India's law creates a special, additional criterion for select technologies, like pharmaceuticals, which could preclude issuance of a patent even if the applicant demonstrates that the invention is new, involves an inventive step, and is capable of industrial application."

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The Food and Drug Administration **issues** guidance for industry and agency staff titled "Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data." Comments may be submitted at any time.

U.S. Senators Amy Klobuchar (D-Minn.) and Bob Casey (D-Pa.) **call** on several pharmaceutical companies to "boost production to end the current shortage of critical drugs used to treat infants in intensive care." According to their May 3, 2013, letter, the shortage involves drugs that provide nutrition to premature and critically ill infants.

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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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