Shook, Hardy & Bacon L.L.P.

ISSUE 9 | MARCH 10, 2011

BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Senate Passes Patent Modernization Bill 95-5

The U.S. Senate has approved the America Invents Act (S. 23), the first major overhaul of the U.S. patent system in more than 50 years. Among other matters, the bill, if approved by the House, will give patent protection to the first to invent, prohibit Congress from diverting U.S. Patent & Trademark Office (USPTO) fees, create a small-business USPTO ombudsman, allow the USPTO to raise fees for applicants, and establish a pilot program for the review of business method patents.

The Senate debated the bill for a week; companion legislation is under development in the House. President Barack Obama (D) issued a statement following the bill's passage, saying, "I'm pleased that, on a bipartisan basis, the Senate has passed the most significant patent reform in over half a century. This long-overdue reform is vital to our ongoing efforts to modernize America's patent laws and reduce the backlog of 700,000 patent applications." He thanked Senators Patrick Leahy (D-Vt.), Chuck Grassley (R-Iowa) and Orrin Hatch (R-Utah) for their leadership on the matter and indicated that he was looking forward to working with the House "to pass patent reform legislation I can sign into law."

U.S. Supreme Court Hears Argument on Patent Rights Under Bayh-Dole Act

A dispute pitting a university against a biotech company over rights to a patent purportedly assigned to the company by the university researcher working on the technology was recently heard by the U.S. Supreme Court. *Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, No. 09-1159 (U.S., argued February 28, 2011). Additional details about the litigation appear in Issue 2 of this *Bulletin.* According to news sources, the Court did not indicate when or how it would rule on the matter, although several justices apparently focused on minor differences in assignment language included in the contracts at issue.

Justice Samuel Alito reportedly noted that the university's position, based on "retaining" rights to inventions it already possesses, runs counter to a basic

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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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patent law tenet, i.e., that inventors have initial title to their inventions. Within the context of the Bayh-Dole Act, he asked, "If the government was going to make such a huge change from normal patent law where the inventor owns his invention until he assigns it to his employer, why wasn't that set forth clearly? All they needed was one paragraph." The Court could issue its ruling before it adjourns at the end of June. *See Law 360*, February 28, 2011; *Stanford Daily.com*, March 1, 2011.

False-Marking Law Under Assault in the Courtroom

A federal court in Ohio has granted a defendant's motion to dismiss a case involving claims for false marking after finding the *qui tam* provision in the false-marking statute unconstitutional. *Unique Prod. Solutions, Ltd. v. Hy-Grade Valve, Inc.*, No. 10-1912 (U.S. Dist. Ct., N.D. Ohio, E. Div., decided February 23, 2011).

Meanwhile, Wham-O, a company sued for falsely marking its Frisbees™ with an expired patent number, has also challenged the constitutionality of the false-marking statute in its appeal to the Federal Circuit Court of Appeals. *FLFMC LLC v. Wham-O, Inc.*, No. 2011-1067 (Fed. Cir., brief filed February 18, 2011). Wham-O's position has garnered the support of the U.S. Chamber of Commerce and the Cato Institute, which have filed *amicus* briefs. Several recent Federal Circuit rulings have apparently spurred hundreds of false-marking lawsuits because the potential damages at $500 per offense, interpreted by the court as per mismarked item, can be significant.

The Ohio court solicited briefing on the law's constitutionality during a hearing on the plaintiff's request to conduct limited discovery on personal jurisdiction. The defendant had initially moved to dismiss the complaint for lack of personal jurisdiction, improper venue and failure to state a claim on which relief can be granted. Thereafter, the defendant filed a motion to dismiss on the ground that 35 U.S.C. § 292(b) violates the Appointments and Take Care Clauses of the U.S. Constitution. The relevant false-marking statute section allows any person to sue for the penalty of $500 per false-marking offense and split the award 50-50 with the United States.

Under the Take Care Clause, the president "shall take Care that the Laws be faithfully executed. The Appointments Clause provides that the executive "shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the Supreme Court, and all other Officers of the United States." According to Hy-Grade Valve, the *qui tam* provision of the false-marking statute violates these clauses because the executive branch lacks sufficient control over the litigation in which the United States is the real party in interest.

Finding that the false-marking statute is criminal, the court applied the "sufficient control" analysis of *Morrison v. Olson*, 487 U.S. 654 (1988), and determined that it was "clear" the government lacks sufficient control to enable that the president "take Care that the Laws be faithfully executed." In fact, the court observed, "The False Marking statute essentially represents a wholesale delegation of criminal law enforcement power to private entities with no control exercised by the Department of Justice." The court further noted, "It is unlike any statute in the Federal Code with which this Court is familiar. Any private entity that believes someone is using an expired or invalid patent can file a criminal lawsuit in the name of the United States, without getting approval from or even notifying the Department of Justice."

The court was also concerned that "this uncontrolled privatization of law enforcement is exacerbated by the financial penalties in this statute. The penalty is up to $500 for each article falsely marked. Depending upon the number of items, this could be a staggering amount of money or a trivial amount." According to the court, the government must "have control over when such cases are brought, and most importantly, how they are settled. Such decisions should be made by government attorneys who have no financial stake in the outcome of the litigation or settlement, not by private parties motivated solely by the prospect of financial gain."

NEW BIO BUSINESS VENTURES

MediciNova and Zhejiang Medicine Announce Joint Venture in China

California-based biopharmaceutical company MediciNova Inc. and Zhejiang Medicine Co., a Chinese pharmaceutical manufacturer, have announced a joint venture to develop and commercialize MediciNova's MN-221 in China. According to MediciNova, "MN-221 is a novel, highly selective, beta2-adrenergic receptor agonist in development as an intravenous treatment for acute exacerbations of asthma and chronic obstructive pulmonary disease (COPD) exacerbations."

"The formation of the Joint Venture Company with Zhejiang Medicine Co., Ltd., provides a unique opportunity to advance the development of MN-221 with a very successful Chinese pharmaceutical partner," MediciNova's chief executive officer said. According to Zhejiang's chair, the joint venture "can provide an enabling path for MN-221 as a promising therapeutic to become available to the millions of patients in China who suffer from acute bronchospasm." *See MediciNova Press Release,* March 3, 2011.

Berg, GNS Announce Joint Venture to Enhance Therapeutic & Diagnostic Development

Massachusetts-based Berg Biosystems, LLC and GNS Healthcare, Inc. have announced a joint venture "to accelerate advancements in critical biomedical research" and reposition "existing drugs for use in new indications with collaborators." Called MAP Biosystems LLC, the joint venture will apparently combine Berg's Interrogative Biology™ drug discovery platform with GNS's patented REFS™ modeling and simulation platform "to unlock the key molecular drivers of complex diseases and drug efficacy and safety."

"MAP represents to biological investigation a new paradigm of physiological understanding based upon a robust network intelligence of disease," Berg president and CTO Niven Narain said. "The unique combination of unbiased systems biology and artificial-intelligence based systems engineering creates a true data-driven approach to therapeutic and diagnostic development." *See Berg Biosystems/GNS Healthcare Press Release,* March 2, 2011.

Agilent Technologies Acquires BIOCIUS Life Sciences

California-based Agilent Technologies has announced the acquisition of BIOCIUS Life Sciences, a Massachusetts-based company that developed a spectrometry device, enabling "researchers to gain a fuller understanding of a drug's biochemical properties, including potential liabilities in drug interactions." Called Rapid Fire™, the device has reportedly been successful at screening "millions of compounds, providing results 10 to 100 times faster than traditional screening methods," according to joint press release.

"BIOCIUS' unique RapidFire technology gives customers an unsurpassed ability to increase the effectiveness and reduce the cost of drug discovery and compound identification," said Agilent's Gustavo Salem. "With this technology and the team that developed it now part of Agilient, we can expand our reach in the pharmaceutical and clinical mass spec markets." *See BIOCIUS/Agilent Press Release,* March 1, 2011.

Research Institution Creates Regional Biomedical Hub in Florida

The Jackson Laboratory, a Maine-based biomedical research institution, has announced a partnership to develop "genetics-based" treatments for heart disease, Alzheimer's disease and diabetes at a new 120,000-square-foot research facility in Sarasota County, Florida. Called The Jackson Laboratory-Florida, the project's partners are the University of South Florida in Tampa, Sarasota Memorial Health Care Systems, Sarasota County, and the Gulf Coast Community Foundation, which, with other community agencies, will "spearhead the creation of a major biomedical village, including research, clinical medicine, education, and residential and retail activity," around the new facility.

Creating a regional biomedical hub "will build the collaborations essential to breakthrough discoveries, clinical medicine and educational outreach," said Jackson's Charles Hewett. "These collaborations will enrich the entire region." Sarasota County officials will apparently seek voter approval to invest county funds in the project, and a referendum may be scheduled as early as July 2011. *See The Jackson Laboratory Press Release,* March 2, 201l.

INVESTOR NEWS

Billionaire Biotech Investor Eyes Synthetic Biology

Virginia biotechnology investor Randal Kirk is reportedly investing in the burgeoning field of synthetic biology, which a recent *Forbes* profile about the billionaire described as "genetic engineering on steroids." Kirk and his investment fund, Third Security, have evidently "poured $200 million into [Intrexon, a] closely held 180-person company in Blacksburg, Va., which has no drugs on the market." Intrexon was founded in 1998 by molecular scientist Thomas Reed, whom Kirk refers to as "the Henry Ford of DNA. We are all living in his dream."

"I've been a biotech investor for 27 years, and Intrexon is by far the best thing I've ever seen," Kirk was quoted as saying. According to the article, synthetic biology, which focuses on reengineering living cells from the ground up rather than making modest genetic changes by adding or deleting single genes, aims to make protein drugs cheaper and more efficient and transform "living cells into tiny molecular factories to make everything from gasoline to construction materials." Kirk is not alone in seeing synthetic biology's potential; J. Craig Venter, who sequenced the first human genome, is also actively involved in the field. *See Forbes,* February 22, 2011.

Osage University Partners Affiliates with Top Universities

Pennsylvania-based Osage University Partners has announced the successful closing of its $100-million debut venture fund, which was created to partner with leading research universities "to license cutting-edge technologies," particularly in therapeutics. Affiliating with universities, such as the California Institute of Technology, Columbia University, Duke University, and Yale University, allows Osage to manage the "coinvestment rights" they hold, giving it contractual access to invest in the most promising startups that license the universities' technologies. The partnership will also enable the institutions to share in Osage's profits to stimulate educational, research and commercialization initiatives. *See Osage University Partners Press Release,* February 24, 2011; *FierceBiotech,* February 25, 2011.

Genomatica Raises $45 Million to Bring Green Chemical to Commercial Scale

San Diego-based Genomatica, a sustainable chemicals company, has reportedly raised an additional $45 million to bring its first green chemical to market with clean-tech investors that include VantagePoint Venture Partners, Bright Capital and Waste Management. Used to make products such as spandex, automotive plastics and running shoes, Bio-BDO is a "green version of 1,4-butanediol (BDO) made from renewable feedstocks rather than oil or natural gas," according to Genomatica.

Genomatica's Mark Burk told a news source that the company, which engineers *E.coli* to convert sugar into BDO, has a pilot facility in Michigan and plans to produce 10,000 liters of the green chemical in 2011. The company reportedly anticipates opening a commercial plant by late 2013. G*enomatica Press Release, Reuters,* March 1, 2011.

BUSINESS CLIMATE

Fewer Small Biotech Companies Go Public

Smaller biotechnology companies maneuvering through drug-development regulations are reportedly focusing their efforts on licensing products in development or selling their businesses to large pharmaceutical companies rather than pursuing an initial public offering (IPO). "There basically isn't an IPO market," J. Scott Tarrant of the product development company RRD International told a news source. "It's pretty much dried up. So the days of a company raising a lot of cash through an IPO . . . and taking products all the way through to market is not standard business practice anymore."

As larger companies trim research and development spending, smaller companies evidently see the opportunity to develop their own technology to attract pharmaceutical giants looking to absorb the technology and move to market quickly. "What I think is becoming more and more the trend is these [biotech] companies not investing in a lot of infrastructure, trying to build value in their products as quickly as possible, so they can attract a deal with pharma," Tarrant said. *See The Washington Post,* February 28, 2011.

India Ponders Domestic Impact of BioPharma Takeovers

According to a news source, recent takeovers of India's key drug companies by foreign pharmaceutical interests have policymakers worried about the potential impact on domestic drug markets and prices. The Indian companies, such as Ranbaxy Laboratories, Dabur Pharma, Shantha Biotech, and Orchid Chemicals and Pharmaceuticals, produce a majority of the less expensive generic drugs and vaccines used in the country and in other developing nations. A paper recently circulated by the commerce ministry reportedly noted that

the takeovers "will further orient [Indian drug makers] away from the Indian market, thus reducing domestic availability of the drugs being produced by them." Other policy analysts apparently suggest that fragmentation in the market keeps competition high and prices low and that the government has the authority to control excessive drug prices. *See Nature Medicine*, February 4, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FDA Advisory Committee Conducts Hearing on DTC Genetic Tests

A Food and Drug Administration (FDA) advisory committee convened March 8-9, 2011, to "discuss and make recommendations on scientific issues concerning direct to consumer (DTC) genetic tests that make medical claims." Among other matters, the panel of experts is considering (i) "risks and benefits of making clinical genetic tests available for direct access by a consumer without the involvement of a clinician," (ii) "risks and possible mitigations for incorrect, miscommunicated, or misunderstood test results," and (iii) what "level and type of scientific evidence [is] appropriate for supporting direct-to-consumer genetic testing claims." Among test categories already proposed to be offered to consumers are genetic carrier screening for hereditary diseases, tests to predict for the future development of disease in currently healthy individuals and tests for "treatment response prediction."

LITIGATION

Ninth Circuit Rules on Jurisdiction in International Biotech Medical Licensing Dispute

The Ninth Circuit Court of Appeals has determined that because the defendants raised an affirmative defense related to an arbitral award falling under an international Convention, a district court had removal jurisdiction. *Infuturia Global Ltd. v. Sequus Pharm., Inc.* No. 09-16378 (9th Cir., decided February 7, 2011). The issue arose in a dispute over medical licensing rights between companies that were citizens of the British Virgin Islands, Israel and California. The technology at issue was developed in Israel "using liposomes as a vehicle for delivering pharmaceuticals to the human body." The licensing agreement included a provision requiring the arbitration of any dispute "connected in any way to the implementation of [the] Agreement."

Legal proceedings arising from the agreement were instituted in a California state court, which granted a stay pending arbitration in Israel. When the arbitration concluded, the state court lifted the stay and the defendants filed a notice of removal to federal court. The district court determined that removal was proper because the litigation related to the arbitration provi-

sion which falls under the Convention on the Recognition and Enforcement of Foreign Arbitral Awards. At issue on appeal was whether removal was improper because the defendants were not parties to the foreign arbitration agreement. The Ninth Circuit adopted a broader reading of the "related to" language of 9 U.S.C. § 205, than urged by the plaintiff and affirmed the lower court.

Seventh Circuit Finds in Favor of Academic on Use of Genetic Sequencing Data

The Seventh Circuit Court of Appeals has ruled that a Dartmouth College bioengineering professor did not commit fraud in obtaining a license to use genome sequencing data and did not breach his written agreement to publish only a limited portion of the data each year by sharing it with his business. ***Integrated Genomics, Inc. v. Gerngross*, No. 09-3718 (7th Cir., decided February 24, 2011)**.

According to the court, while the professor was not entirely forthcoming about his dual affiliation, the plaintiff failed to introduce sufficient evidence to show that it would have charged the professor a significantly higher licensing fee had it known the data would be used by his company. The court also determined that the agreement's publication restriction was intended to apply to public dissemination of the data and not to its communication to the professor's company. So ruling, the court affirmed a lower court determination.

DNA Sequence Analysis Company Can Proceed in Non-Compete Action Against Former Employee

A federal court in Michigan will allow a company's claims that a former employee allegedly breached a non-competition agreement to proceed. *Gene Codes Corp. v. Thomson*, No. 09-14687 (U.S. Dist. Ct., E.D. Mich., S. Div., decided February 11, 2011). The company develops software to analyze DNA sequences and convert them into readable computer data. The employee worked at the company for about 10 years and "performed a variety of roles related to product development, sales and technical support." Her responsibilities were reduced and her compensation was cut in half about a year before she left the company due to a corporate restructuring and the employee's "lackluster" performance. In her final role as "global manager," the employee worked in technical support with limited access to the company's customer database.

The employee took a position with a competitor, which developed a different DNA sequencing software product, and her new job involved marketing and selling this product. She allegedly contacted 24 of her former company's clients. The company sued her alleging that she violated state uniform trade secrets law and breached her employment agreement's non-compete clause.

The court dismissed the trade secrets claims finding that no reasonable jury could conclude that the former employee misappropriated the company's trade secrets because the company "failed to identify any particular customer list that Defendant could potentially misappropriate."

The court allowed the breach of contract claim to proceed finding that "a material fact exists as to whether [the current employer] is a 'direct competitor' within the meaning of the non-compete clause." The claim will be limited, however, with the court finding that the non-solicitation clause "is enforceable only as to customers that Defendant herself successfully solicited on behalf of Plaintiff or with whom Defendant had built up goodwill while working for Plaintiff." The court also indicated that it was inclined to allow some limited additional discovery as to the interpretation of the term "customer" in the non-solicitation clause. According to the court, it was unclear whether entire institutions, individual departments or individual scientists were within the term's ambit.

Patent Agent Pleads Guilty to Passing Insider Info About Biotech Company

A former biotech company patent agent and his brother have reportedly entered guilty pleas to charges of providing insider tips to others in a conspiracy to violate securities fraud laws. According to a news source, when Aaron Scalia was employed by Sequenom, Inc., he allegedly told his brother Stephen that the company was about to announce that data on its prenatal Down syndrome test was unreliable and later told him that the company planned to buy Exact Sciences.

In each case, the information was purportedly provided with the knowledge that it "would be used to purchase stocks or stock options." Stephen apparently passed the knowledge to a college friend whose uncle then made a gross profit of $600,000 by using the inside information in stock trades. Sentencing before a federal court in California is reportedly scheduled for April 29, 2011.

NEWS BYTES

The Federal Trade Commission releases a **report** examining the effect that "patent trolls," or "patent assertion entities" in agency-speak, have on competition. The report recommends improvements to policies and procedures and mechanisms for courts to improve patent law remedies.

The U.S. Patent & Trademark Office **announces** a pilot project for the Patent Prosecution Highway with the Mexican Institute of Industrial Property. This work-sharing program is designed to expedite examination and improve patent quality.

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The U.S. Patent & Trademark Office (USPTO) co-hosts a women's entrepreneurship symposium with the U.S. Women's Chamber of Commerce for Friday, March 11, 2011, in honor of Women's History Month. Government leaders, including U.S. Senator Mary Landrieu (D-La.) and newly appointed USPTO Deputy Director Teresa Stanek Rea, were scheduled to address symposium participants.

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Intellectual Property Partner Peter Strand will lead a session on communicating with jurors at DRI's Business Litigation and Intellectual Property Seminar slated for April 14-15, 2011, in Chicago, Illinois. Titled "A Thousand Words More or Less: Effectively Using Visuals at Trial," the presentation will address "the 'whys' and 'hows' of teaching and persuading jurors using the entire panoply of visual media."

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