Shook, Hardy & Bacon L.L.P.

ISSUE 22 | OCTOBER 6, 2011

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

U.S. Supreme Court Opens 2011-2012 Term with IP Cases on Its Docket

The U.S. Supreme Court returned for a new term on October 3, 2011, with two of the 48 cases already calendared for oral argument involving IP matters. The Court will hear *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, No. 10-1150, on December 7 to consider whether "a patent claim that covers observed correlations between blood test results and patient health" is valid. Additional information about the Federal Circuit Court of Appeals ruling in the case appears in Issue 5 of this *Bulletin*, and details about the U.S. Supreme Court's grant of the Mayo Clinic's certiorari petition appear in Issue 16.

In *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, the Court will consider a Federal Circuit interpretation of the Hatch-Waxman Act in the context of whether a generic drug maker can file a counterclaim in a patent infringement lawsuit to correct information the brand name manufacturer submitted to the Food and Drug Administration (FDA). According to the petitioner, the Act "allows generic drug makers to market a drug for specific uses not claimed by any patent. But FDA lacks the expertise needed to determine whether particular uses are patented, so it defers to brand-name drug companies' descriptions of the scope of their patents." Here, the Federal Circuit apparently determined that the Act's "counterclaim provision authorizes 'delet[ing]' improperly listed patents but not 'correct[ing]' information that misrepresents the scope of the patent." The Court has scheduled oral argument in this case for December 5.

While an argument date is yet to be determined, the Court has agreed to hear a case asking whether an inventor may introduce new evidence in a section 145 civil action if the evidence was available when her patent application was filed and whether the court must defer to the U.S. Patent and Trademark Office on the factual issues to which the new evidence relates. *Kappos v. Hyatt*, No. 10-1219. More detail about the case appears in Issue 16 of this *Bulletin*.

Shook, Hardy & Bacon L.L.P.

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

ISSUE 22 | OCTOBER 6, 2011

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.

For additional information on SHB's Life Sciences and Biotechnology capabilities, please contact

Patrick Henderson
Corporate Transactions
816-559-2115
phenderson@shb.com

Chris Johnson
Life Sciences & Biotechnology
415-544-1900
cjohnson@shb.com

Madeleine McDonough
Pharmaceutical & Medical Device
202-783-8400
mmcdonough@shb.com

Thomas Moga
Intellectual Property
202-639-5622
tmoga@shb.com

If you have questions about this issue of the Report, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

NEW BIO BUSINESS VENTURES

Teva Pharmaceuticals Acquires Remaining Half of Japanese Joint Venture for $150 Million

Israel-based Teva Pharmaceutical Industries Ltd. has announced that it has purchased the 50 percent interest of its Japanese joint venture partner Kowa Co. Ltd. for $150 million. According to a press release, Teva and Kowa established Teva-Kowa Pharma Co., Ltd. in September 2008, "and have since grown the joint venture into one of the top 5 generic players in Japan," with sales of approximately $200 million in 2010.

"We are happy to have reached this agreement to bring all our Japanese operations under Teva's full control and ownership," said Shlomo Yanai, Teva's president and CEO. "With this stronger platform, Teva will be in a better position to further drive penetration of high quality generic pharmaceuticals in Japan and make better healthcare accessible to the Japanese people." The latest deal is expected to generate annual sales in excess of $800 million, according to the company. *See Teva Pharmaceutical Industries Press Release,* September 26, 2011.

Mesoblast, Lonza Group Agree to Mass Produce Stem Cell Drugs

Australia-based Mesoblast Ltd. and Switzerland-based Lonza Group have formed an alliance "for clinical and long-term commercial production of Mesoblast's off-the-shelf (allogeneic) adult stem cell products." According to a joint press release, Mesoblast can require that Lonza build a dedicated manufacturing facility for its products in exchange for "agreed quantities" of those products.

Mesoblast "holds worldwide exclusive rights for a series of patents and technologies relating to adult Mesenchymal Precursor Cells," and Lonza "is a global leader in the production and support of active pharmaceutical ingredients both chemically as well as biotechnologically." Lonza CEO Stefan Borgas said that the cell therapy market "is anticipated to become a major growth industry with the potential to mirror the growth we have seen in monoclonal antibodies over the past 20 years." *See Mesoblast/Lonza Joint News Release,* September 26, 2011.

INVESTOR NEWS

St. Louis-Area Coalition Commits $30 Million to Bioscience Research

Washington University, BJC HealthCare and St. Louis Life Sciences Project have reportedly committed $30 million in research funding over the next five years to promote bioscience research in the region. The coalition, BioSTL, is headed

by Donn Rubin, who said, "This commitment positions the region to capitalize on opportunities to create and attract enterprises and jobs in a significant high growth 21st century industry." Most of the funds will apparently be dedicated to pre-seed and seed investments as well as associated support for startups. The initiative continues a decade of work by the Coalition for Plant and Life Sciences. *See Washington University News Release*, September 27, 2011.

ViroPharma Buys License Rights to Drug Molecule for $6.5 Million

Biotech ViroPharma Inc. has announced that it has paid $6.5 million to New York-based Intellect Neurosciences, Inc. for worldwide licensing rights to a clinical-stage drug candidate called OX1. The drug is under development to treat a rare, hereditary, progressive neurodegenerative disease, known as Friedreich's Ataxia (FA), which is linked to a range of symptoms from gait disturbance to speech problems and can also lead to heart disease and diabetes. Apparently, no FA treatments are currently approved by the Food and Drug Administration.

According to the agreement, ViroPharma, headquartered in Exton, Pennsylvania, "will pay additional milestones based upon defined events," with a maximum payout up to $120 million. The biopharmaceutical company will also reportedly "pay a tiered royalty of up to a maximum percentage of low teens, based on annual net sales." *See ViroPharma News Release,* September 30, 2011.

Elevation Pharmaceuticals Garners $17 Million Tranche for Series A Financing

Elevation Pharmaceuticals Inc. has announced positive results from a Phase 2a study of new aerosol therapy for patients with moderate to severe chronic obstructive pulmonary disease (COPD) that generated a $17-million second tranche of its Series A financing. The funding will be used for an ongoing Phase 2b study, "for which top-line results are projected to be available by the end of the first quarter 2012," according to an Elevation press release. All the original participants have participated in the second tranche—Canaan Partners, Care Capital, TPG Biotech, and Mesa Verde Venture Partners.

Elevation describes its drug, EP-101, as "a proprietary inhalation solution formulation of glycopyrrolate, a long-acting muscarinic antagonist (LAMA), delivered by an optimized, investigational eFlow® Nebulizer System." According to Senior Vice President and Chief Medical Officer Ahmet Tutuncu, "the positive results from this single dose Phase 2a study and the patients' positive experience with the investigational eFlow device support further development of EP-101 for the unmet need in COPD patients." *See Elevation Pharmaceuticals Press Release,* September 26, 2011.

NABsys Raises $10 Million in Series C Round for DNA-Analytic Technology

Rhode Island-based NABsys, Inc., which uses technology licensed from Brown University and was founded by a Brown physics professor, has announced that it has raised $10 million for continued technology development and marketing of solid-state electronic systems for single-molecule DNA analysis. Led by Stata Venture Partners, the Series C Preferred Stock financing brings to more than $21 million the total funding raised since April 2009.

The life science company's "vision is to power DNA sequencing and analysis by using solid-state systems coupled with innovations in chemistry and algorithms to achieve unprecedented levels of accuracy, speed and cost." DNA structural variation, sequencing of targeted genes and whole-genome sequencing will be addressed by the solid-state systems.

Eli Upfal, a NABsys consultant and Brown computer science professor, told a news source that a significant part of the funding will go toward jobs, with other portions slated for new machinery and software. NABsys CEO Barrett Bready was quoted as saying that a semiconductor-based system for single-molecule DNA sequencing and analysis "is designed to provide information not attainable from other DNA sequencing platforms, enabling an array of new research and clinical applications." *See NABsys News Release,* September 14, 2011; *The Brown Daily Herald,* September 22, 2011.

BUSINESS CLIMATE

Illinois Industry Groups Sign Memorandum of Cooperation with Chinese Counterpart

According to Illinois Governor Pat Quinn (D), the Illinois Science & Technology Coalition and iBIO, a state-based life-sciences industry association, have entered a memorandum of understanding with the Shanghai Bio Pharmaceutics Association. Speaking during an economic and business trade mission in China, Quinn said, "Illinois and China are each leading global sources for biotechnology, life sciences and medical innovation. This agreement provides a framework for Illinois and China to enhance business and education partnerships and collaborate on the scientific breakthroughs that will accelerate company growth and foster the creation of jobs."

The governor's office has indicated that academic research expenditures in bioscience disciplines reached $1.3 billion in the state in 2008, and some 58,000 workers are directly employed in that sector by more than 2,000 biotech establishments. Six of the top 20 pharmaceutical and life sciences companies apparently maintain their North American headquarters in Illinois. *See Gov. Quinn Press Release*, September 22, 2011.

Industry Report Claims Massachusetts Biotechs Continue to Grow

The Massachusetts Biotechnology Council (MassBio) has issued an annual report claiming that the commonwealth "continues to outpace other states and countries for biotechnology industry growth and investment." The "2011 MassBio Biotechnology Industry Snapshot" asserts that biopharma jobs in Massachusetts totaled 48,000 in 2010, with 26,000 in research and development. According to the report, the commonwealth's biotech companies received "an all-time high" 23.1 percent share of all U.S. investment capital last year, with startup and seed-stage investments surpassing 2002 and 2006, previous years for which data were available

Other highlights in the report include that (i) Massachusetts' 2010 record biopharma industry employment accounts for a $4.6 billion payroll, (ii) biopharma companies headquartered in the commonwealth account for about 10 percent of the U.S. drug development pipeline and 5 percent of the global pipeline, and (iii) Middlesex County has the greatest number of biotechnology researchers in the country, with Suffolk, Essex and Worcester counties among the highest. *See MassBio Press Release,* September 27, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

BIO Supports New Legislation Reducing SEC Paperwork Burdens for Small Startups

A bipartisan bill (S. 1544), introduced in early September 2011, has reportedly gained the support of Biotechnology Industry Organization (BIO) President and CEO Jim Greenwood. Sponsored by Senators Jon Tester (D-Mont.) and Patrick Toomey (R-Pa.), the proposal would amend the Securities Act of 1933 to allow companies to sell up to $50 million in shares through a public offering without filing lengthy paperwork with the Securities and Exchange Commission. The proposed legislation, titled the "Small Company Capital Formation Act of 2011," was referred to the Committee on Banking, Housing, and Urban Affairs. Similar legislation (H.R. 1070) was introduced in the House in March, reported out of committee with an amendment and placed on the Union Calendar on September 14.

Commenting on the measure, Greenwood said, "Raising the exemption to $50 million would greatly help cash-strapped companies that are short on resources to raise much-needed capital through public offerings without an extended paperwork process. The biotech industry is overwhelmingly made up of small businesses that are founded by entrepreneurs and supported largely by private capital." *See BNA Life Sciences Law & Industry Report,* September 23, 2011.

FDA Issues Draft Guidance on *De Novo* Classification Process for Medical Devices

The Food and Drug Administration (FDA) has issued draft industry and staff guidance pertaining to its *de novo* classification process, which "provides a route to market for medical devices that are low to moderate risk, but that have been classified in class III because FDA has found them to be 'not substantially equivalent' (NSE) to legally marketed predicate devices." The guidance, distributed for public comment only, explains when the process may be used, how *de novo* information and the *de novo* petition should be submitted, and the process that staff will use to review these petitions. While comments on the guidance may be submitted at any time, they are requested by December 2, 2011, for consideration in FDA's preparation of the final guidance document. *See Federal Register*, October 3, 2011.

LITIGATION

Monsanto Co. Wins Patent Infringement Claims Against GE Soybean Farmer

The Federal Circuit Court of Appeals has determined that farmers who plant the progeny of genetically engineered (GE) soybean seeds protected by U.S. patents have infringed those patents even where the progeny are derived from commodity seed purchased from a grain elevator. ***Monsanto Co. v. Bowman*, No. 2010-1068 (Fed. Cir., September 21, 2011)**. The defendant farmer purchased GE seeds from a Monsanto licensee and signed a technology agreement that restricted him from saving any crop produced from the seed for replanting. He purchased and planted seeds containing Monsanto's Roundup Ready® technology as his first crop in each growing season from 1999 through 2007. He did not save seed from his first crop during any of those years.

In 1999, the defendant also purchased commodity seed from a local grain elevator for second-crop, or late-season, planting. Because late-season crops are riskier, the farmer bought the less expensive commodity seed for planting. He found that many of these plants were glyphosate-resistant, as were the GE seeds he had purchased from a Monsanto licensee. From 2000 through 2007, he continued to treat his second-crop with glyphosate-based herbicide and, unlike his first crop, the farmer saved the seed harvested from his second crop for replanting additional second crops in later years. He also apparently supplemented his second-crop planting supply with occasional additional purchases of commodity seed from the grain elevator. He was open about these practices in correspondence with Monsanto representatives.

Monsanto sued the defendant for patent infringement in 2007, and, upon investigating eight of his fields, or about 299 acres, confirmed that his second-crop soybean seeds, the progeny of the commodity seeds, contained Roundup Ready® technology. According to the court, the farmer's tech-

nology agreement extended only to seeds purchased from Monsanto or a licensed dealer, and, thus, his use of the commodity seeds was not within the agreement's scope. Also, "Monsanto did not allege infringement or breach of the Technology Agreement with respect to [the defendant's] planting of first-generation seeds purchased from [the licensee]." A federal district court granted Monsanto's motion for summary judgment and awarded the company nearly $84,500. The defendant appealed, arguing that "Monsanto's patent rights are exhausted with respect to all Roundup Ready® soybean seeds that are present in grain elevators as undifferentiated commodity."

Monsanto argued that licensed growers' sales of second-generation seeds to grain elevators as commodity seeds does not exhaust the company's patent rights under the express conditions of the technology agreement. According to the company, "a grower's sale of harvested soybeans to a grain elevator is not an 'authorized sale' when it results in those soybeans subsequently being planted." The appeals court agreed, noting, "Even if Monsanto's patent rights in the commodity seeds are exhausted, such a conclusion would be of no consequence because once a grower, like [the defendant], plants the commodity seeds containing Monsanto's Roundup Ready® technology and the next generation of seeds develops, the grower has created a newly infringing article."

Third Edition of Judicial Science Guidelines Published

The Federal Judicial Center and National Research Council have issued the third edition of the ***Reference Manual on Scientific Evidence***, which courts use to understand complex expert testimony and scientific evidence produced at trial. The manual is available online at no charge; it aims to provide judges with a background on undisputed scientific matters so they are prepared to either admit or exclude expert testimony in pending litigation. Consisting of 1,038 pages, the manual includes several new chapters on scientific evidence, unavailable when it was first published in 1994. According to a U.S. district court judge who co-chaired the committee that oversaw the third edition's production, the new chapters address advances in neuroscience research and forensic science. *See The BLT: The Blog of LegalTimes*, September 30, 2011.

NEWS BYTES

The Food and Drug Administration **seeks** comments about the recordkeeping burdens relating to conformity with good manufacturing practices for finished pharmaceuticals. Comments on the collection of information are requested by October 28, 2011.

The Food and Drug Administration (FDA) **requests** nominations for a nonvoting industry representative to serve on the Vaccines and Related Biological Products Advisory Committee for the Center for Biologics Evalua-

LIFE SCIENCES
& BIOTECHNOLOGY
LEGAL BULLETIN

ISSUE 22 | OCTOBER 6, 2011

tion and Research. A nominee may be either self-nominated or nominated by an organization. FDA requests letters of interest and nomination materials by October 31, 2011.

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Intellectual Property Attorney Thomas Moga will be serving as the moderator for a panel discussion on "Protections of Biotechnology Inventions in China, US and Europe: A Comparative Perspective," during BIO China, the BIO International Convention in Shanghai, China, October 12-13, 2011. Shook, Hardy & Bacon is co-sponsoring this event, which will feature exhibits, networking opportunities and programs on patent enforcement, biosimilar innovation, clinical trials, and global trends in vaccine development. Moga's panel features Jasemine Chambers, the U.S. Patent and Trademark Office's deputy administrator for external affairs, Francisco Javier Fernández y Brañas, director biotechnology of the European Patent Office, a representative of the Chinese Patent Office, and Chris Sappenfield, senior counsel for Ibis Biosciences, Inc., who will discuss how legislative and regulatory changes have affected biotechnology patenting in three jurisdictions.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
London, England
+44-207-332-4500
Washington, D.C.
+1-202-783-8400
San Francisco, California
+1-415-544-1900
Irvine, California
+1-949-475-1500
Houston, Texas
+1-713-227-8008
Kansas City, Missouri
+1-816-474-6550
Miami, Florida
+1-305-358-5171
Tampa, Florida
+1-813-202-7100

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

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.