Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Standing Issue Back in Play in *Myriad Genetics*

While the Federal Circuit Court of Appeals has ordered the parties in *Molecular Pathology v. U.S. Patent and Trademark Office* (*Myriad Genetics*) to address the effect of the U.S. Supreme Court's *Prometheus Laboratories* ruling on the validity of the composition and method patents at issue in *Myriad Genetics*, the defendant, which holds an exclusive license to the patents, has once again raised whether the challengers have standing.

Myriad Genetics has filed a suggestion of mootness or a motion to remand, arguing that the lone plaintiff with standing has left the clinic where he was previously employed and "now works at unrelated institutions. Myriad has never had any communications with those institutions regarding the challenged patents; indeed, unlike the situations with NYU [New York University] in 1998, Myriad has no knowledge whatsoever of what, if any, activities those institutions have engaged in or engage in presently. Accordingly, Dr. Ostrer's change in employment mooted any real or immediate dispute that might otherwise have been before this Court."

Myriad requests that the court dismiss the appeal, which was remanded to the Federal Circuit by the U.S. Supreme Court, or remand the case for the district court to make a determination on standing. At issue is whether isolated DNA is patent eligible; additional information about the case and the Federal Circuit's split ruling appears in Issue 18 of this *Bulletin*.

NEW BIO BUSINESS VENTURES

New Stem Cell Research Center to Open in India

Banaras Hindu University (BHU) in Uttar Pradesh, India, will reportedly establish a research center focused on stem cells and bone marrow transplants. The 10-bed Stem Cell Research and Bone Marrow Transplantation Centre, scheduled to open in 18 months, is expected to target new treatments for cancer,

and cardiovascular and auto-immune diseases. "There are not many centers in the country that carry out such stem cell research," BHU's vice chancellor was quoted as saying. "In Uttar Pradesh, though there is sporadic research going on, no such organized state-of-the-art facility is available." *See The Indian Express*, June 4, 2012.

LabCorp Acquires MEDTOX for $241 Million

Laboratory Corporation of America® Holdings (LabCorp), which offers more than 4,000 diagnostic tests including genomic testing, has announced that it will acquire MEDTOX Scientific, a company that provides specialized laboratory testing services, for a purchase price of $27 per share in cash, a total value of approximately $241 million. The board of directors of MEDTOX, based in St. Paul, Minnesota, reportedly approved the agreement and recommended approval by the company's shareholders. "MEDTOX is an industry leader in specialized toxicology testing," said LabCorp Chair and CEO David King. "This acquisition provides a strong foundation for growth in this business, as we build and expand LabCorp's Toxicology Center of Excellence and add to the unrivaled assets of the LabCorp Specialty Testing Group." *See Business Wire,* June 4, 2012.

INVESTOR NEWS

Agendia Garners $65 Million in Financing Round to Develop Diagnostic Tests

Agendia, a molecular cancer diagnostics company, has reportedly raised $65 million in a private round of equity financing led by the Debiopharm Group™, a Swiss drug-development company. Along with new investors, other financial support came from all of Agendia's current investors, including The Van Herk Group, ING Corporate Investments, Breedinvest, and Gilde Healthcare. "We will use these funds to expand commercialization of our current breast cancer Symphony™ suite of tests, as well as for development of our personalized medicine pipeline," said Agendia CEO David Macdonald, adding that the company is preparing to launch ColoPrint, a "recurrence test for stage II colon cancer prognosis and prediction." *See Agendia Press Release*, May 31, 2012.

Non-Profits in Patient Advocacy Community Invest Millions in Drug Development

Halo Therapeutics, which is developing a drug with promise in the treatment of Duchenne muscular dystrophy (DMD), a disease that leads to early death in young boys, reportedly raised $1.1 million in a new funding round that included money from 12 non-profit foundations. According to a news source, the drug's main ingredient is an herb that has long been used in Chinese medicine. CEO Marc Blaustein noted that the drug, which was once tested

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as an anti-malaria compound by the U.S. military, has key attributes that can address the muscle degeneration seen in DMD patients: it can reduce the harmful buildup of collagen in muscles, reduce inflammation and promote muscle regeneration.

While Halo's funding includes traditional grants, the notes issued to patient advocacy non-profits offer a fixed return based on specific milestones. Blaustein said, "If Halo adds value and we can repay that money, we want to offer [the groups] the opportunity to use it to develop other therapeutics. We want to put the value back into the patient community." He called the participation of so many non-profits unusual, but said that the model "holds some real promise."

Meanwhile, the Susan G. Komen for the Cure foundation has apparently provided a $4-million grant to researchers at Washington University in St. Louis and the Institute of Cancer Research in London studying the use of genomic information to identify which breast cancer patients are most likely to experience disease recurrence and to identify therapies that are most effective for those women. *See Halo Therapeutics Press Release,* May 22, 2012; *Xconomy*, May 24, 2012; *GenomeWeb*, June 4, 2012.

Medical Device Co. Completes $26-Million Financing Round

SentreHEART Inc., a privately held medical device company based in Redwood City, California, has recently completed a $26-million Series C financing round led by Vivo Ventures with participation by its existing investors US Venture Partners and Prospect Ventures. SentreHEART will use the funds to commercialize its LARIAT® Suture Delivery Device, which "facilitates suture placement and knot tying for use in surgical applications where soft tissues are being approximated and/or ligated using a pre-tied polyester suture."

According to President and CEO Paul Buckman, the technology "is being rapidly adopted by physicians around the world," and its "ongoing clinical and commercial successes confirm the market need for soft tissue closure without the expense and morbidities associated with traditional open surgeries." The device, he noted, "has the potential to transform certain open surgical procedures traditionally performed in the operating room into more cost-effective procedures that can be performed in the catheterization lab, where only a small piece of suture is left behind." *See SentreHEART Press Release*, June 4, 2012.

Zurex Pharma Raises $6.2 Million for Antimicrobial Product Development

Wisconsin-based Zurex Pharma has reportedly secured $6.2 million in Series A financing led by Baird Venture Partners and the State of Wisconsin Investment Board. Zurex plans to use the capital to develop and market antimicrobial

products designed to prevent infections in hospitals and homes, focusing on surgical-site wounds and catheter-related infections. "The increasing concern on hospital and home care safety, particularly in relation to health-care acquired infections, leads to a very compelling market opportunity for Zurex," said Michael Liang of Baird Venture Partners. "The Zurex team has a strong track record of developing innovative medical products and bringing them to market." *See Zurex Pharma Press Release*, May 22, 2012.

Novan Therapeutics Raises $5.1 Million to Advance Nanoparticle Technology

Novan Therapeutics, a University of North Carolina at Chapel Hill biotech spinoff, has reportedly raised $5.1 million in new equity funding, with the financing possibly expanding to $11 million, according to a recent U.S. Securities and Exchange Commission filing. Novan evidently raised $6 million in fall 2011. According to a news source, Novan was founded in 2008 by researchers focusing on nitric oxide-releasing nanoparticle technology for uses ranging from improvements to immune system response and wound healing to blood pressure control. The recent financing will evidently be used to further clinical development of NVN1000, a topical gel used to treat acne. *See MedCity News*, June 1, 2012.

BUSINESS CLIMATE

U.S. Set to Approve More Cancer Drugs in 2012; 1,000 Said To Be in Development

Speaking at a meeting of the American Society of Clinical Oncology, Richard Pazdur, who leads the Food and Drug Administration's (FDA's) Office of Hematology and Oncology Products, reportedly indicated that the agency expects more than 20 oncology drug applications to be filed in 2012, a significant increase over last year when just 10 drugs were approved to treat cancer. Some attribute the rapid rise to a better understanding of the disease's molecular makeup. Pazdur noted that oncology drugs are unique because the regulatory emphasis is on efficacy rather than safety given how sick cancer patients often are. He also apparently indicated that the agency is now meeting with drug developers earlier and more frequently in the approval process.

In another report from the society's Chicago meeting, drug makers are now apparently testing nearly 1,000 drugs to treat cancer. According to the analysis provided by the Pharmaceutical Research and Manufacturers of America, these therapies, in clinical trials or under FDA review, include more than 100 each for lung cancer, lymphoma and breast cancer. Steady improvements in cancer survivorship have apparently been seen in the United States

with mortality falling 22 percent for men and 14 percent for women between 1990 and 2007, representing almost 900,000 fewer deaths. *See Online Pharma-Times*, June 1, 2012; *Reuters*, June 4, 2012.

U.S. Could Lose Leadership of Biopharma R&D

A study recently released by the Battelle Technology Partnership Practice contends that without a dedicated governmental commitment to biopharmaceutical research in the United States, other countries, relying on U.S. funding and regulatory models, will outpace its leadership role in this sector.

According to the report, the U.S. biopharmaceutical sector directly and indirectly supported 4 million jobs in 2009 at wages more than twice the average private-sector wage. The sector's economic "output" also apparently totaled in excess of $917 billion in 2009. Among the emerging economies that have developed plans to grow the biopharmaceutical sector are Brazil, Chile, China, Russia, Saudi Arabia, Singapore, South Africa, and South Korea. Most of the countries studied for the report "have in place a national plan or strategy to guide investment designed to cultivate a knowledge-based economy."

The report concludes that the United States, to maintain its leadership, must increase its investments in research and development (R&D), as well as "commercialization, education and workforce development, financial capital, and the nation's science and technology infrastructure."

In a related report, concerns were expressed about the United States losing its global leadership in the life sciences. Titled "Leadership in Decline: Assessing U.S. International Competitiveness in Biomedical Research," the report was discussed during a congressional briefing in May 2012. Noting that federal funding for biomedical research peaked in 2003, the report "documents the foundational role public investment plays in underpinning a nation's competitiveness in the life sciences," "assesses the intensifying competition for global life sciences leadership through case studies of four countries," and calls for Congress to fund the National Institutes of Health "consistently at a level representing at least 0.25 percent of GDP." If Congress does not meet budget targets, NIH funding could be cut 7.8 percent, or $2.4 billion in fiscal year 2013. *See Bloomberg BNA Life Sciences Law & Industry Report*, June 1, 2012.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

House Passes FDA Funding Bill

The U.S. House of Representatives approved legislation (H.R. 5651) on May 30, 2012, that, among other things, would revise and extend the user fees that industry pays the Food and Drug Administration (FDA) to expedite safety reviews of new medicines and medical devices.

The U.S. Senate earlier approved its version of the FDA funding bill, which must be reconciled by both chambers before the current version expires in September. The fees, first enacted in 1992, must be renewed every five years. According to a news source, the legislation could raise user fees by more than $2 billion from the previous five-year period, with the fees equaling nearly half of FDA's proposed $4.5-billion budget next year. *See Reuters* and *Bloomberg,* May 31, 2012.

"Gray-Market" Bill Targets Drug Shortages and Price Gouging

Representative Elijah Cummings (D-Md.) has introduced a bill (**H.R. 5853**) designed to reform the process in which "gray market" drug companies buy drugs in short supply and then resell them at drastically marked-up prices. The Gray Market Drug Reform and Transparency Act of 2012 would prohibit wholesalers from purchasing prescription drugs from pharmacies and "enhance information and transparency regarding drug wholesalers engaged in interstate commerce."

According to Cummings, ranking member of the House Committee on Oversight and Government Reform, the bill "includes several provisions to address weaknesses in the drug supply chain, deter price gouging, and improve drug safety and efficacy." Among other things, it would (i) create a national database for wholesalers to report information, such as the status of their state licenses, and establish penalties for false reports or incomplete information; (ii) encourage state regulators to provide "key information" about wholesalers operating in their states; and (iii) require companies selling drugs on the U.S. Food and Drug Administration's "list of drugs in critically short supply to include in pedigrees transmitted to buyers the sales price of those drugs" so that buyers have information about the drugs' markups.

"Nobody should be allowed to engage in profiteering at the expense of children and adults with cancer or other critical illnesses by jacking up the price of drugs that are in critically short supply," Cummings said. "This bill closes down loopholes in the supply chain and ensures that consumers have more information about who is handling their drugs." *See Representative Elijah Cumming Press Release*, May 22, 2012.

Pharmacists Focus on Biosimilar Substitutions in FDA Draft Guidance Comments

Pharmacy trade groups have urged the Food and Drug Administration (FDA) to allow pharmacists to substitute biosimilar drugs for their biologic counterparts without physician approval if the agency has already determined that they are interchangeable. In a May 25, 2012, **letter**, the American Pharmacists Association, National Association of Chain Drug Stores and National Commu-

nity Pharmacists Association also claim that FDA should not require separate names for biosimilars and biologics because of the undue confusion it would cause consumers and pharmacies.

"When a biosimilar product is approved by the FDA as interchangeable to its reference product, we have confidence that the FDA made that decision after thorough consideration," the letter states. "Therefore, we believe that if the FDA deems interchangeability between products, pharmacists should be able to automatically substitute biosimilar interchangeable products as [interchangeable product substitution] is currently regulated under the [Public Health Service] Act."

Draft Stem Cell Research Guidelines Issued in India

The Indian Council of Medical Research and Department of Biotechnology have released proposed stem cell research guidelines that are intended to clarify stakeholder responsibilities, delineate rules on pre-clinical and clinical trials, and widen regulations to include banking of biological tissues and stem-cell imports and exports.

The draft guidelines, released in March and open for public comment, deal specifically with research rather than therapy. They address the procurement of gametes, embryos and somatic cells in a responsible and ethically sensitive manner and categorize stem cell research into three areas: permissible, restricted and prohibited. The guidelines also state that "clinical use of stem cells as standard of care, outside of approved clinical trials, is not permitted . . . [u]ntil the indications, efficacy and long term safety of the procedure is established." This provision was reportedly included to stop the practices of health-care providers who claim to offer stem cell-based therapy in the country. Oversight parameters are also outlined in the proposal. *See Bloomberg BNA Life Sciences & Industry Report*, May 18, 2012.

LITIGATION

Eighth Circuit Allows Investor Suit to Proceed Against Pharmaceutical Co.

The Eighth Circuit Court of Appeals has determined that investors alleging securities fraud against a pharmaceutical company which claimed in its Securities and Exchange Commission filings that it was in material compliance with Food and Drug Administration (FDA) regulations sufficiently pleaded that the claims were false or misleading. ***Public Pension Fund Group v. KV Pharm. Co.*, No. 10-3402 (8th Cir., decided June 4, 2012)**.

In this regard, the court rejected the company's claim that the receipt of a Form 483 from FDA "can never render a company's statements about compliance with FDA regulations or cGMP [current good manufacturing practice] false or misleading." The company had argued that such forms lack any indicia of finality, stating on their face that the listed observations made by FDA inspectors "are inspectional observations, and do not represent final Agency determination regarding . . . compliance."

According to the court, the issuance of a Form 483 "may render a defendant's statement about its compliance with FDA regulations or cGMP false, or at least misleading, in some circumstances. The FDA's issuance of Form 483s may be material depending on a number of factors, including the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted by the FDA. There is a substantial likelihood the presence of these factors would be viewed by a reasonable investor as significantly altering the total mix of information made available, irrespective of whether the Form 483 represents the FDA's final say on compliance issues."

The Eighth Circuit reversed the district court's dismissal as to this claim, but upheld the dismissal of several other claims. The appellate court also found that the district court abused its discretion in denying the plaintiffs' post-judgment motion to amend their complaint and remanded the matter for further proceedings.

Court Upholds Drug Profit Sharing; Pharma Co. Breached Agreement to Negotiate Deal

A Delaware court has issued a letter opinion finalizing its 2011 ruling requiring SIGA Technologies Inc. to share profits from its smallpox drug with PharmAthene, Inc. *PharmAthene, Inc. v. SIGA Techs, Inc.*, No. 267-VCP (Del. Ch., decided May 31, 2012). All profits will be evenly split after SIGA makes its first $40 million, a remedy apparently similar to the framework discussed while the companies were negotiating a merger and licensing deal. The court previously determined that SIGA breached the companies' agreement to negotiate the deal. According to a news source, PharmAthene was pleased with the court's ruling, particularly in light of news provided to SIGA investors that the U.S. Department of Health and Human Services expects to begin purchasing the drug in the first quarter of 2013 as a defense to potential bioterrorism attacks. *See Law360*, June 1, 2012.

Advocacy Coalition Agrees to Drop Nanotechnology Lawsuit Against FDA

A coalition of advocacy organizations has reportedly agreed to dismiss as moot its lawsuit seeking an order requiring the Food and Drug Administration (FDA) to respond to its 2006 petition asking the agency to regulate products

containing nanomaterials. Information about the lawsuit appears in Issue 422 of Shook, Hardy & Bacon's *Food & Beverage Litigation Update*. The organizations, including Food and Water Watch and the Institute for Agriculture and Trade Policy, apparently indicated that while the agency has rejected some of their key proposals, FDA has formally responded to the petition. FDA has said that it will not regulate nanomaterials as new substances, but will evaluate them based on their effects on foods, drugs and cosmetics. *See Capital Press*, May 18, 2012.

NEWS BYTES

The Food and Drug Administration issues guidance on preclinical safety evaluations of biotechnology-derived pharmaceuticals. Comments may be submitted at any time.

The Food and Drug Administration seeks public comments on a proposed collection of information submitted for Office of Management and Budget approval on the burden of submitting biosimilar applications under section 351(k) of the Biologics Price Competition and Innovation Act of 2009. Comments are requested by June 25, 2012.

The U.S. Patent and Trademark Office issues proposed regulations for establishing micro-entity status under the America Invents Act. Micro entities are entitled to pay 75-percent reduced patent application fees. Comments are requested by July 30, 2012.

The U.S. Patent and Trademark Office seeks comments on "the international effort to revise the standard for the presentation of nucleotide and/or amino acid sequences and the consequent changes to the United States rules of practice." Proposed ST.26 would "require the use of extensible mark-up language (XML) format, to update the standard and to more closely align requirements of the standard with those of public sequence database providers." Comments are requested by July 16, 2012.

The National Biodefense Science Board announces a June 26, 2012, public meeting in Washington, D.C., to discuss the "development of a national public health and healthcare situational awareness strategy and implementation plan." The board will also address its new task of identifying and evaluating the anticipated responsibilities of the Strategic National Stockpile for the year 2020.

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FIRM NEWS

Shook, Hardy & Bacon IP attorneys John Garretson and Elena McFarland have co-authored an article appearing in the June 1, 2012, issue of *Corporate Counsel*. "It's (Not) Only Natural" discusses the U.S. Supreme Court's *Mayo v. Prometheus* decision and a subsequent U.S. Patent and Trademark Office memorandum to patent examiners about continued use of existing guidance on patentable subject matter. They provide practical tips for practitioners concerned about the patent eligibility of claims involving diagnostic activity.

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