Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

SCOTUS Hears Arguments on Patentability of Human Genes

The U.S. Supreme Court (SCOTUS) heard **arguments** on Monday specifically addressing whether "human genes are patentable." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398 (U.S., argued April 15, 2013). The Federal Circuit Court of Appeals decision from which the appeal was taken affirmed its earlier ruling, in the wake of *Mayo Collaborative Services v. Prometheus, Inc.*, 132 S. Ct. 1289 (2012), that isolated DNA molecules were patent eligible and that most of Myriad's "method claims" for comparing molecules to determine whether a patient's genes have mutations that could cause breast and ovarian cancer were not patent eligible. Further details about the Federal Circuit's ruling appear in Issue **41** of this *Bulletin.* An opinion is expected by the end of June 2013.

While Justice Antonin Scalia questioned whether a company would "incur massive investment if it cannot patent," Justices Sonia Sotomayor, Stephen Breyer and Anthony Kennedy all questioned counsel about the narrow, middle ground suggested by the Obama administration, which has called for the court to void parts of the patents while allowing other aspects to be upheld. The U.S. Solicitor General argued that Myriad is not entitled to a patent on "isolated DNA," but may be entitled to patent synthetic DNA molecules, which require skilled human manipulation to produce.

With the potential for the Court's decision to have a wide impact on science, medicine, biotechnology, and basic research, the industry is watching the case closely, and several dozen *amicus* briefs were filed in the case. Some believe that it could pose obstacles to personalized medicine and whole-genome sequencing if the Court upholds the validity of individual gene patents. Other Court watchers suggest that any ruling may have limited effects because much of the human genome has been sequenced and put into the public domain, and many of the patents that have been awarded to date involve selective isolation of specific DNA stretches. *See USA Today*, April 10, 2013; *Nature*, April 11, 2013; *The New York Times*, April 14, 2013; *Bloomberg,* April 15, 2013.

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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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M&A DEALS

$13.6 Billion Deal to Merge Rival Genetic-Sequencing Machine Companies

Thermo Fisher Scientific has reportedly agreed to purchase Life Technologies Corp. for $13.6 billion in a deal expected to close in early 2014. Waltham, Massachusetts-based Thermo Fisher has apparently offered Life Technologies' shareholders $76 for each of their shares and will assume some $2.2 billion in debt. Life Technologies, located in California, makes more than 50,000 different types of scientific equipment, including gene-sequencing and DNA-analysis machines. According to a news source, it reported $3.8 billion in revenue in 2012. The deal will allow Thermo Fisher to expand its market share in the manufacture of genetic-sequencing machines, a high-growth industry in the new era of personalized medicine. Thermo Fisher CEO Marc Casper said, "The acquisition of Life Technologies enhances all three elements of our growth strategy: technological innovation, a unique customer value proposition and expansion in emerging markets." *See The New York Times DealBook*, April 15, 2013.

INVESTOR NEWS

Tetragenetics Inc. Receives $826 Million Grant for Malaria Vaccine

Tetragenetics Inc. has received an $826-million Phase 2 grant as well as new partnerships with two drug companies, according to a news source. The Cambridge, Massachusetts-based early-stage biotech will reportedly use the new grant, which comes from a Bill & Melinda Gates Foundation-backed initiative, to build on a Phase 1 grant that aims to develop an improved malaria vaccine that can be taken orally.

Company Chair Doug Kahn told a news source that its "technology is based on a process of producing proteins using Tetrahymena, an animal-like cell that can be grown in pure culture. There are now about a half-dozen ways to create such large-molecule drug candidates, one of the most common of which relies on using Chinese hamster ovary, or CHO, cells." *See Boston Business Journal.com*; *Tetragenetics Inc. News Release,* April 3, 2013.

Cancer Genetics IPO Raises $6.9 Million

Rutherford, New Jersey-based Cancer Genetics, Inc., an early-stage diagnostics company that develops genomic-based, oncology tests and services, has announced that its initial public offering (IPO) of 690,000 shares of common stock closed at $10.00 per share, raising $6.9 million, before expenses. In a Form S-1/A filed with the Securities and Exchange Commission on April 1, 2013, the company stated that "the proprietary tests [it is developing] target

cancers that are difficult to prognose and predict treatment outcomes by using currently available mainstream techniques. These cancers include hematological, urogenital and HPV-associated cancers."

Some $2 million of the IPO's net proceeds will evidently go toward funding the company's joint venture with the Mayo Foundation for Medical Education and Research to develop oncology diagnostic services and tests using next-generation sequencing, reports a news source. *See Genomeweb.com,* April 5, 2013; *Cancer Genetics, Inc. News Release,* April 10, 2013.

Heat Biologics Secures $5 Million in Equity

According to press reports, Heat Biologics has raised $5 million that it will use to continue evaluating HS-110® in Phase II clinical trials as a treatment for non-small cell lung cancer and to initiate additional clinical trials for a bladder cancer treatment later in 2013. The Chapel Hill, North Carolina-based biotech's securities filings indicate that the funding is a mix of equity and options, warrants and rights to acquire other securities. A total of 20 investors evidently participated in the offering.

The company has developed a proprietary technology it calls Immune Pan-Antigen Cytotoxic Therapy®—or ImPACT—which purportedly reprograms live tumor cells to continually produce antigens designed to prompt the immune system to fight disease. Heat Biologics reportedly said that it intends to use ImPACT to make off-the shelf vaccines for a general patient population rather than personalized drug therapies that are patient specific. *See Heat Biologic News Release,* March 15, 2013; *WralTechWire.com,* April 10, 2013.

Syros Pharmaceuticals Raises $30 Million for Cancer Research

Newly launched life sciences company, Syros Pharmaceuticals, has announced a $30 million Series A financing round led by company co-founders ARCH Venture Partners and Flagship Ventures. The company plans to use the capital "to accelerate the discovery and development of novel gene control medicines," called super super-enhancers. The Watertown, Massachusetts-based company's proprietary platform "identifies the master switches for disease genes, opening a whole new approach to novel therapeutics." The company's initial focus is on cancer, but it reports that the platform will also be applicable to other therapeutic areas.

"It is increasingly clear that much of human diseases lies in the switches that control genes rather than the genes themselves," Richard Young, one of the company's three co-founders, said. "We have identified super-enhancers with key cancer driving genes in all tumors studied and have demonstrated that we can selectively disrupt these genes through inhibition of enhancer factors. Given the complexity of gene expression, the discovery of a small number of powerful gene control regulators provides a promising and exciting new

approach to understanding key determinants of cell identity in normal and disease states." *See Syros Pharmaceuticals News Release*; *Boston Business Journal,* April 11, 2013.

Biotech Secures $5.3 Million for Immunosuppressant Drug Research

San Francisco-based startup, Nurix, Inc., which reportedly develops T-cell-specific immunosuppressants used to treat autoimmune diseases such as rheumatoid arthritis, lupus, multiple sclerosis, and psoriasis, has evidently secured $5.3 million in equity funding from four investors, according to a securities filing. Nurix is apparently backed by a group of venture investors, including The Column Group and Third Rock Ventures. *See MedCity News,* April 4, 2013.

Crop Biotech Company Secures $14.5 Million in Series A Financing

A private company that develops agricultural products designed to improve crop productivity has reportedly raised $14.5 million in a Series A financing round to further advance its research and development programs. Located in Research Triangle Park, North Carolina, AgBiome LLC is focused on the identification of novel microbes and new, useful genes from those microbes. Chief Scientific Officer Dan Tomso said, "Microbes associated with agricultural ecosystems are a nearly infinite source of useful new genes and biologicals. AgBiome aims to become the world leader in agricultural discovery centered around these resources." The company's first product is apparently a biological that can control the "predominant soil-borne diseases of greenhouse and major row crops," and it is working to apply state-of-the-art genomics and screening technologies to find plant-associated plant-health, pest-resistance and yield-enhancement microbes. *See AgBiome LLC News Release*, April 11, 2013.

Cleave Biosciences Secures $10 Million to Support Cancer Therapies

Cancer drug developer, Cleave Biosciences Inc., has secured $10 million in Series A financing from new investor New Enterprise Associates (NEA), bringing the biotech's total financing from this round to $54 million. The Burlingame, California-based company said it "will use the funds to move the company's lead program into clinical trials and advance its second discovery program."

Cleave Biosciences discovers and develops "novel small molecule therapies for difficult-to-treat cancers." According to a news release, the company "has developed first-in-class drug candidates against novel targets in protein degradation pathways, including the ubiquitin proteasome and autophagy systems." Cleave is also apparently "using molecular profiling approaches with the goal of identifying patient subsets most likely to benefit from each of its targeted drugs."

CEO Laura Shawver said, "These targets Cleave is pursuing have the potential to have wide therapeutic impact for people who have cancers dependent on protein degradation for their survival. NEA joins us at an exciting time as we continue our progress to identify clinical candidates, as well as determine which subsets of cancers can best be addressed using the Cleave strategy." *See Cleave Biosciences News Release,* April 9, 2013.

BUSINESS CLIMATE

VC, Private Financing Still Hard to Find for Omics/MDx Firms

Companies developing diagnostics (MDx) and "omics" technologies (e.g., genomics, epigenomics, proteomics, metabolomics), used as predictors of clinical outcomes, are reportedly continuing to face obstacles attracting venture capital (VC) and private funding. According to a VC company spokesperson, "Until we see exits that are substantially larger than what we've been seeing, the value of the exit does not justify a huge amount of investment." Epic Sciences President and CEO David Nelson echoed those comments, noting "The returns or the market sizes that have been achieved with traditional diagnostic companies are not the same as the therapeutic companies. There are very few billion dollar-type product opportunities in diagnostics. And that's certainly one thing that venture capitalists look at, that sort of home run."

Just one omics/MDx company reportedly went public in 2012; several others have withdrawn their IPOs, let their IPOs lapse or delayed launch. Despite the interest in new omics technology, investors have learned that getting a company to the commercial stage can be costly. Another VC insider said, "It gets good press," but two omics/MDx companies that went public in 2010 reportedly spent more than $100 million to get to market and they are "still not profitable." Macroeconomic factors affecting the industry include the 2008 economic downturn, ongoing budget battles and sequestration in Washington, D.C., as well as a purported unpredictable reimbursement environment under health-care reforms. The mergers and acquisitions pipeline has also apparently been depressed. *See GenomeWeb*, April 1, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

President's Budget Proposes Banning "Pay for Delay" Agreements

The pharmaceutical industry has weighed in on President Barack Obama's proposed 2014 fiscal year budget, finding much to criticize, including a provision that would prohibit the owners of prescription drug patents from entering settlement agreements with generic competitors paying to delay the generic's entry into the market in return for the dismissal of patent

invalidity litigation. Other budget proposals would reduce the exclusivity period of biologic medicines from 12 to seven years and prevent biologics "evergreening," that is, extending patent protection by taking out new patents for altered delivery systems or new mixtures of patented drugs. The Pharmaceutical Research and Manufacturers of America (PhRMA) called the proposal "bad for patients, bad for innovation and bad for the economy." While the president's budget is not expected to be enacted, it does establish a number of bargaining positions for the congressional negotiations to come. *See PhRMA Press Statement*, April 10, 2013.

House Bill to Allow Tax Credit for Investment in High Tech and Biotech Companies

U.S. House representatives have reintroduced the Innovative Technologies Investment Incentive Act (**H.R. 1415**), a bill that would "amend the Internal Revenue Code of 1986 to allow a credit for equity investments in high technology and biotechnology small business concerns developing innovative technologies that stimulate private sector job growth."

Bill sponsor Rep. C.A. Dutch Ruppersberger (D-Md.) said that the proposed legislation "will create jobs, accelerate economic growth, and make targeted investments that keep America on the cutting edge of innovation."

"In Maryland, the growing life sciences sector—which includes many small biotechnology firms—has generated one third of all job gains over the past decade and this bill will enable them to expand and hire even more," noted Ruppersberger. "It's exactly the type of common sense jobs bill that lawmakers should be focused on right now."

Rep. Chris Van Hollen (D-Md.) said of the proposal, "As our economy continues to recover, the Innovative Technologies Investment Incentive Act will provide an important boost to America's most innovative small companies at a time when that boost is needed most. Putting Americans back to work is our number one priority. This pro-growth initiative—modeled after the highly successful Maryland Biotechnology Investment Incentive Tax Credit and similar legislation in other states—will leverage private capital to create good-paying jobs, reward innovation, and lay the foundation for our future prosperity."

Introduced on April 9, 2013, bill would (i) "accelerate innovation by providing a 25 percent tax credit for qualified equity investments in eligible high technology and biotechnology small business concerns"; (ii) "invest in quality by directing credit-qualified investments only to those small businesses that have met the federal government's rigorous requirements for receiving Small Business Innovation Research (SBIR) grant awards"; (iii) "control costs by establishing a per company cap for the Innovative Technology Investment Credit at one half the value of the receiving company's SBIR award and an initial program cap of $500 million"; and (iv) "reward long term investments

by requiring a holding period of at least three years for qualified investments." *See Reps. C.A. Dutch Ruppersberger* and *Chris Van Hollen News Releases,* April 9, 2013.

Congress Takes FDA to Task for Inaction over Fungal Meningitis Outbreak

A House Energy and Commerce subcommittee **questioned** Food and Drug Administration (FDA) Commissioner Margaret Hamburg on April 16, 2013, about the agency's oversight of compounding pharmacies as part of an ongoing congressional investigation into FDA's response to a fungal meningitis outbreak that purportedly resulted in 53 deaths and sickened more than 700.

The committee has also released a staff **report** based on a review of thousands of FDA documents. According to Oversight and Investigations Subcommittee Chair Tim Murphy (R-Pa.), the documents show that the agency had been notified before the outbreak by doctors, patients, providers, and whistleblowers about questionable practices and conditions at the New England Compounding Center, which produced the drugs linked to the outbreak, but "focused on perfecting [its] legal reasons for inaction instead of protecting families."

Rep. Edward Markey's ((D-Mass.) staff issued a **report** titled "State of Disarray: How States' Inability to Oversee Compounding Pharmacies Puts Public Health at Risk." Its premise is that with pharmacies under the jurisdiction of state regulators and given conflicting judicial rulings regarding FDA's authority over compounding pharmacies, Congress must act to give the agency the necessary authority to avoid future outbreaks. The report summarizes findings from House Democrats' investigation of state boards of pharmacies and concludes that "most states are incapable of assuring the safety of compounded drugs [and] . . . poor record-keeping practices by the states make it difficult, if not impossible, for the states to identify compounding pharmacies with systemic, repetitive compounding safety problems."

The Congressional Research Service (CRS) has also released a report on the regulation of compounded drugs. Titled "Federal Authority to Regulate the Compounding of Human Drugs," the April 12 report provides a brief history of drug regulation in the United States and notes that FDA did not historically use its authority under the Food, Drug, and Cosmetic Act (FDCA) to regulate compounding because "it was widely recognized that compounded drugs could not meet the FDCA's 'new drug' requirements. As the [U.S.] Supreme Court has noted, subjecting compounding pharmacies to the statute's approval requirements 'would as a practical matter, eliminate the practice of compounding, and thereby eliminate availability of compounded drugs for those patients who have no alternative treatment.'"

According to the CRS report, courts "that have examined the issue have all agreed that the FDA has *some* authority to regulate compounding. Specifically, case law appears to find that the FDCA does provide the federal government with the authority to prohibit pharmacists from manufacturing under the guise of compounding." Still, "the legislative history of the FDCA appears to support the view that manufacturers were the intended target of the regulatory scheme imposed by the 1938 act," and that its enactment did not disturb the traditional approach to pharmacies which are subject to state oversight. The CRS report concludes, "absent further congressional action, the limits of the FDA's authority to regulate all forms of compounding will likely continue to be unresolved."

Meanwhile, FDA has issued a **statement** to report that it has conducted 29 of 31 priority inspections of compounding pharmacies and concluded that most employed sterile drug-production practices that create a risk of contamination. Among FDA's observations were "incomplete and/or inadequate drug product batch failure investigations, inappropriate and/or inadequate clothing for sterile processing, lack of appropriate air filtration systems, and insufficient microbiological testing." FDA coordinated most of the inspections with state oversight officials because it does not have authority over those compounders operating within the bounds of traditional pharmacy compounding and indicated that it will refer appropriate cases to state regulators for enforcement. *See 2013 FDA Pharmacy Inspection Assignment*, April 11, 2013.

Silicon Valley Companies Welcome New USPTO Outpost

The U.S. Patent and Trademark Office (USPTO) has begun hiring judges who will staff its Silicon Valley regional office and expects to eventually hire hundreds of patent examiners. Michelle Lee, recently appointed to head the office, reportedly said that its goal "is to provide easier and more convenient access to the application process for everyone." While a permanent location has yet to be confirmed, Lee and other hires are working now from temporary Menlo Park offices. When it opens, the Silicon Valley office will join others established under the America Invents Act and evaluate patents from all over the country not just from the regions in which they are located. It is possible, however, that certain work will be funneled through specific offices; for example, the Silicon Valley outpost could eventually handle software and semiconductor patents exclusively. During a recent presentation, Lee said that the regional office will provide applicants in-person access to their patent examiners which will help streamline the process and reduce the application backlog. *See Corporate Counsel*, April 16, 2013.

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LITIGATION

Strand Launches IP Damages Litigation Blog

Shook, Hardy & Bacon Intellectual Property (IP) Partner **Peter Strand**, who authors *IpQ*, a complimentary monthly newsletter focusing on comprehensive analyses of patent damages issues, has launched a related law **blog** to offer "top-line thinking about top-of-mind IP damages topics." Titled "IpDamQuick: Enhancing Your IP Damages IQ™," the blog allows Strand to address the latest IP litigation developments with "concise commentary on their immediate effect and possible long-term impact." Recent topics include cases on damages experts, royalties, discovery on damages, and the entire market value rule (EMVR).

NEWS BYTES

The U.S. Department of Commerce **announces** the winners of the U.S. Patent and Trademark Office's Patents for Humanity pilot program. The awards program recognizes "patent owners and licensees who address global challenges in health and standards of living." The categories include medical, food and nutrition, clean tech, and info tech.

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