Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
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IP NEWS

Myriad Genetics Brings New BRCA1/BRCA2 Infringement Suits

Myriad Genetics now reportedly has six pending infringement lawsuits involving its BRCA1 and BRCA2 patents, with Invitae Corp. and Laboratory Corp. most recently named as defendants. According to a news source, Myriad has asked to consolidate all of the lawsuits in Salt Lake City, Utah, including the three in which it has been named as a defendant. Invitae filed its suit in a federal court in California just one day after Myriad sued the company in a Utah federal district court. Invitae asserts 22 claims for relief, challenging the validity of 11 Myriad patents and seeking declarations of non-infringement. *Invitae Corp. v. Myriad Genetics, Inc.*, No. 13-5495 (U.S. Dist. Ct., N.D. Cal., filed November 26, 2013).

Invitae alleges that its "comprehensive test offers the sequencing of over 200 human genes, all for less than the cost of what others might charge for a test that sequences one or two." It also claims that it "performs its sequencing using a very different approach than that claimed by the Myriad patents." Contending that its different approach "is not covered by any valid claim of a Myriad Patent," Invitae notes that "[a] vast portion of the landscape purportedly claimed by the Myriad Patents has been washed away in the wake of . . . Federal Circuit and [U.S.] Supreme Court[] decisions" and that "the mere method of 'comparing' or 'analyzing' (i) the genetic sequence data from a patient with (ii) another sequence, such as a reference or wild type sequence, or a sequence having a known mutation, is patent ineligible as an abstract idea, and also patent ineligible as a law of nature."

Invitae co-founder Randy Scott said, "We believe the Supreme Court rulings validate Invitae's view that no company can claim ownership over naturally occurring genetic information. Our suit is based on the teachings of these cases. The legal process will take its course, and we are steadfast in our resolve." *See Invitae Corp. News Release*, December 2, 2013; *The Salt Lake Tribune*, December 9, 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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INVESTOR NEWS

Cancer Therapeutics Startup Raises $120 Million

In what is apparently one of the largest Series A investments ever for a biotech startup, Juno Therapeutics has reportedly raised $120 million in a Series A financing round. A Seattle, Washington-based joint venture between Fred Hutchinson Cancer Research Center (Fred Hutch), Memorial Sloan-Kettering Cancer Center and Seattle Children's Research Institute, Juno develops novel immunotherapies for late-stage cancer patients. The deal was led by Arch Venture Partners and the Alaska Permanent Fund through a partnership managed by Crestline Investors.

Juno plans to build on recent breakthroughs in novel immunotherapy design to develop two distinct and complementary platforms—chimeric antigen receptors and T-cell receptors, which the company reports can reduce longer-term toxicities associated with current chemotherapeutics and provide the potential for curative therapy even for patients with wide-spread disease.

Commenting on Juno's launch, Fred Hutch President and Director Larry Corey said, "The longtime research investment that centers like the Fred Hutchinson Cancer Research Center and Memorial Sloan-Kettering have had in tumor immunology has allowed us to progress to where we feel we can genetically engineer smart T cells to eradicate malignant cancer cells and provide meaningful clinical remissions. Joining together allows us to bring some of the world's most accomplished immunotherapy researchers to catalyze this field." *See Juno Therapeutics News Release,* December 4, 2013.

Biodesix Closes Series E Financing for Cancer Test

Biodesix, Inc., a Boulder, Colorado-based molecular diagnostics developer, has closed an $8.3- million Series E financing round. New funds accounted for $4.3 million of the round, and $4 million came from the conversion of a convertible note. The company plans to use the funds to develop its technology platform and to expand sales and marketing efforts for its first product, VeriStrat®, a serum protein test that helps doctors "guide therapy for patients with advanced non-small cell lung cancer (NSCLC)."

"Biodesix is a growing company with a strong pipeline," said CEO David Brunel. "In securing this investment we are well positioned to effectively deliver game changing diagnostics to guide physician decisions and improve patient outcomes." *See Biodesix, Inc. News Release*, December 3, 2013.

$45 Million Raised to Aid Development of Obesity Drug

Cambridge, Massachusetts-based Zafgen, Inc. has secured $45 million in a Series E equity financing round that the company will use to continue development of its obesity therapeutic, beloranib, which reportedly demonstrated in a Phase 2 study that it helped bring about significant weight loss in 147 people. New investors RA Capital Management, Brookside Capital, Venrock, Alta Partners, an undisclosed blue chip investor, and a private investor joined previous backers in the round.

"We are excited to add this group of new investors to our syndicate and to obtain continued investment from Alta Partners who led our Series D round last year, as we continue to advance our clinical testing for beloranib in severe obesity and related orphan indications," said Zafgen President and CEO Thomas Hughes. "With their support, we look forward to building on our recent Phase 2 results and expanding the beloranib program to help patients who suffer from these serious diseases."

Beloranib reportedly works by blocking an enzyme, methionine aminopeptidase 2 (MetAP2), that makes fatty acids, which in turn reduce hunger and the production of new fatty acid molecules by the liver, helping convert stored fats into energy. *See Zafgen, Inc. News Release* and *BizJournal.com,* December 4, 2013.

Alvotech Invests $250 Million in Biopharmaceuticals

According to news sources, Alvotech, the Reykjavik, Iceland-based sister company of multinational pharmaceutical Alvogen, plans to invest $250 million to develop and manufacture biosimilar monoclonal antibodies. The funds will reportedly be used to pay for an 11,800-square-meter manufacturing facility in Iceland, slated to open in 2016, where Alvotech plans to produce its own developed biosimilars.

Through the Alvotech-Alvogen alliance, Alvogen will reportedly add key pipeline molecules to its existing biosimilar business. "Many of the world's top-selling drugs are biologics, and exposure to biopharmaceuticals has become an important growth engine for Alvogen. The alliance with Alvotech will allow us to leverage our global commercial network in over 30 countries and is an important step for both companies towards becoming leaders in the biopharmaceutical industry. The partnership is a valuable addition to our current biosimilar business," said Alvogen Chair and CEO Robert Wessman. *See FiercePharmaManufacturing.com,* December 6, 2013.

UBC Researchers Receive $7.2 Million to Develop Pulmonary Disease Test

Two University of British Columbia (UBC) researchers have received CAN$7.2 million (US$6.8 million) to develop a test that will identify patients at risk for lung attacks brought on by chronic obstructive pulmonary disease (COPD). A progressive disease, COPD is characterized by loss of lung function that can lead to breathlessness, poor quality of life, loss of productivity, and increased mortality. Reportedly the fourth leading cause of death in Canada and a leading cause of hospital admissions, COPD can be exacerbated by severe lung attacks that apparently provide no advance warning and whose symptoms can resemble pneumonia, heart attacks or the flu.

Noting that doctors now "blindly treat all patients the same way regardless of how active their disease is because we have no test that can tell us about the disease's intensity or activity," scientists leading the project say the test will help medical professionals provide better treatment and ultimately reduce hospitalizations and emergency visits. The four-year project, which is funded by Genome BC, Genome Canada, PROOF Centre of Excellence, St. Paul's Hospital Foundation, and Genome Quebec, will use genomic technologies to identify biomarkers from 1,000 COPD patient samples. *See UBC News Release,* December 5, 2013.

BUSINESS CLIMATE

Can Biotech Investor Confidence Continue?

Nature Biotechnology Business Editor Brady Huggett recently examined the 2013 surge in biotechnology initial public offerings (IPOs) and considers whether and how long it may last. According to venture-capital experts, the surge was predicted a year ago, after Facebook's IPO made many investors wealthy, and new money moved down the line to biotech stocks. Given better performance by mature biotech companies, as well as JOBS Act provisions allowing companies to communicate with investors before public disclosure of a potential IPO and the U.S. Food and Drug Administration's accelerated approval of biologics in 2012, "the frantic pace of IPOs" apparently combined to help biotechs "go[] supernova in 2013." Still, some do not compare the current pace with "the zeal in 2000," when even "mom-'n-pop retail investors" were seeking to cash in on the news about decoding the human genome. While the surge is not yet over, some expect that pent up demand will be satisfied, investment money will be used up and the market will return "to a period of normal, natural growth" by the third quarter of 2014. *See Nature Biotechnology*, December 2013.

European Markets Less Than Enthusiastic over Biosimilars

While Europe has had a regulatory approval pathway for biosimilar drug products for some years, their use reportedly remains anemic. Physicians are apparently reluctant to prescribe them, despite the lower costs, and companies developing them have evidently had problems recruiting enough subjects for clinical trials and in creating products "similar" enough to the complex reference biotech drugs. According to a press report, Norway will fund clinical studies that switch patients from the original drug to biosimilars in 2014 to demonstrate that the latter are just as effective. Health ministries across Europe will watch the trials closely due to the significant savings that biosimilars offer. The IGES Institut in Berlin has apparently estimated that biosimilar use could save up to 33.4 billion euros (US$45.5 billion) across Europe by 2020. Currently, biosimilars account for less than 0.5 percent of biotechnology drug spending in developed markets, although some countries, such as Germany, provided a stronger market for biosimilars than others. *See Reuters*, December 3, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

President Signs Compounding-Pharmacy Legislation; FDA Rolls Out Draft Guidance

Shortly after President Barack Obama signed the Drug Quality and Security Act (H.R. 3204) into law, the U.S. Food and Drug Administration (FDA) issued draft guidances for industry to provide direction on its implementation: (i) "**Interim Product Reporting for Human Drug Compounding Outsourcing Facilities**," (ii) "**Registration for Human Drug Compounding Outsourcing Facilities**," and (iii) "**Pharmacy Compounding of Human Drug Products.**"

Comments on each are requested by February 3, 2014. Additional information about the legislation appears in Issue **68** of this *Bulletin*.

The agency also issued requests for nominations of "**bulk drug substances that may be used to compound drug products**" and "**specific drug products or categories of drug products" presenting "demonstrable difficulties for compounding**."

Nominations for each list are requested by March 4, 2014. These requests relate to outsourcing-facility exemption provisions requiring FDA to establish such lists. *See Federal Register*, December 4, 2013.

House Approves Patent-Reform Legislation

In a bipartisan 325-19 vote, the U.S. House of Representatives has approved a bill (**H.R. 3309**) intended to curb litigation abuse by "patent trolls." Chief sponsor Rep. Bob Goodlatte (R-Va.) reportedly said during floor debate, "This bill is something I consider central to U.S. competitiveness, job creation and our nation's future economic security." It would strengthen patent-infringement pleading requirements, shift costs to the losing party and create new discovery rules. While the measure would express the sense of Congress that "purposely evasive demand letters" constitute an abuse of the patent system and include a provision requiring study of their effects, the legislation would impose no further requirements on those sending such letters. The bill now moves to the Senate, where revisions are apparently anticipated. Among the concerns expressed by the bill's opponents are that the pleading requirements could keep legitimate inventors out of court and fee shifting could favor wealthy parties and chill claims with merit. *See The Blog of LegalTimes* and *Ars Technica*, December 5, 2013.

FDA Orders 23andMe to Stop Selling DNA Tests

The U.S. Food and Drug Administration (FDA) **issued** a warning letter in late November 2013 to 23andMe, Inc., the company that marketed a home "Saliva Collection Kit and Personal Genome Service" designed to provide a DNA analysis from the sample and inform consumers whether they are at risk of developing certain diseases. According to FDA, the product is a medical device "because it is intended for use in the diagnosis of disease or other conditions" and requires the agency's pre-market approval under the Food, Drug, and Cosmetic Act. FDA also expressed concern with false positive or negative assessments and the potential for "patients relying on such tests [to] begin to self-manage their treatments through dose changes or [abandonment of] certain therapies." Four other personal-genomics companies also received warnings on November 22 that they require preapproval for their products.

According to a news source, 23andMe has discontinued providing the service to new customers, but will maintain access to the health-related reports already generated for customers before the warning letter issued. Those who purchased the products before November 22 will also apparently continue to receive their results. Saying that the company remains committed to helping people access their genetic data, co-founder and CEO Ann Wojcicki said, "Our goal is to work cooperatively with the FDA to provide that opportunity in a way that clearly demonstrates the benefit to

people and the validity of the science that underlies the test." Meanwhile, less than a week after the letter was sent, a putative consumer-fraud class action was filed against 23andMe. Additional details about the litigation appear elsewhere in this *Bulletin. See Law360,* December 2, 2013; *genomeweb.com*, December 6, 2013.

LITIGATION

Consumer-Fraud Class Action Filed Against 23andMe After FDA Action

Citing the Food and Drug Administration's (FDA's) November 22, 2013, warning letter, a California resident has filed a putative class action against 23andMe, Inc., alleging that its DNA-analysis service is falsely marketed to consumers because the company lacks "analytical or clinical data to support the device's efficacy." *Casey v. 23andMe, Inc.*, No. 13-2847 (U.S. Dist. Ct., S.D. Cal., filed November 27, 2013). The plaintiff alleges on behalf of a putative nationwide class of consumers that the company claims its $99-test kit and analysis can provide information about more than 240 health conditions and traits thus enabling planning for the future if children are at risk for inherited conditions, documenting family health history and providing doctors with information that could be useful in prescribing medications.

According to the complaint, FDA has worked with the company since 2009 to address regulatory requirements and obtain marketing authorization, but that the agency still lacks assurance that the firm has analytically or clinically validated the product for its intended uses. The complaint also notes that the company uses the "meaningless" test results by sharing with other sources "and the scientific community in general."

Alleging violation of the "unfair," "fraudulent" and "unlawful" prongs of California's Unfair Competition Law, violations of the False Advertising Law and Consumers Legal Remedies Act, breach of warranty of merchantability and fitness for a particular purpose, unjust enrichment, deceit by concealment, and negligent misrepresentation, the plaintiff seeks equitable relief; actual, statutory and punitive damages; attorney's fees; costs; and interest.

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UPCOMING CONFERENCES AND SEMINARS

The Product Quality Research Institute, U.S. Pharmacopeial (USP) Convention and American Association of Pharmaceutical Scientists have **scheduled** a nanotechnology workshop for January 14-15, 2014, at the USP Meeting Center in Rockville, Maryland. Titled "Nanomaterial Drug Products: Current Experience and Management of Potential Risks," the workshop will feature presentations by industry representatives, academics and government regulators.

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