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# LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS



## FIRM NEWS

### Dunne to Address Litigation Risks Related to Molecular Diagnostics at ABA Workshop

Pharmaceutical & Medical Device Partner **Debra Dunne** will join a distinguished panel during an October 9, 2014, American Bar Association (ABA) Section of Litigation continuing legal education **workshop** in Austin, Texas. Titled "Regulation of Molecular Diagnostics and Potential Litigation Issues," the panel discussion will focus on the U.S. Food & Drug Administration's existing bifurcated regulatory pathway for molecular diagnostic tests, including laboratory-developed tests, and draft agency guidance meant to simplify the requisite steps for approval by adopting a risk-based process. The event was organized by the Products Liability Committee's Medical Device and Pharmaceutical Subcommittees.

## IP NEWS

### Australian Court Finds Human Gene Mutation to Be Patentable

A full panel of the Federal Court of Australia has upheld its earlier ruling that an isolated but naturally occurring nucleic acid, BRCA1, can be patented. ***D'Arcy v Myriad Genetics Inc.*, FCAFC 115 (Fed. Ct. of Austl., decided September 5, 2014)**. The decision stands in contrast to the U.S. Supreme Court's conclusion in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, No. 12-398 (2013), which determined that human genes and the information they encode are not patentable even if isolated, thus invalidating certain Myriad BRCA1 and BRCA2 claims based solely on isolation. Additional information on that decision appears in Issue **59** of this *Bulletin*.

Shook, Hardy & Bacon L.L.P.

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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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After discussing the BRCA1 patent and the underlying science, the court compared the claims in the Australian patent to Myriad's claims in its invalidated U.S. patent, finding them to be different. The court also noted that the U.S. Congress had not considered the issue, while "Parliament has considered the question of the patentability of gene sequences and has chosen not to exclude them." To further distinguish the Australian and U.S. patent systems, the Australian court noted that the High Court has rejected an approach eliminating "products of nature" from patentability, while the United States prohibits the patenting of such material.

Explaining its reasoning, the Australian court responded to the U.S. Supreme Court and Federal Circuit decisions on BRCA1 and BRCA2 patentability, finding the circuit court's opinion upholding the patents more persuasive. "What is being claimed is not the nucleic acid as it exists in the human body, but the nucleic acid as isolated from the cell. The claimed product is not the same as the naturally occurring product. There are structural differences but, more importantly, there are functional differences because of isolation," the court said. "It is the chemical changes in the isolated nucleic acid which are of critical importance, as this is what distinguishes the product as artificial and economically useful."

## JOINT VENTURES

### Belgian Company Forms Joint Venture, Raises Funds to Expand Cancer Diagnostics

Molecular diagnostics company Biocartis NV has reportedly completed a €64.5 million (US$85 million) private equity fundraising round to support its roll-out of Idylla™, a fully automated diagnostics platform. It has also formed a joint venture with protein diagnostics company Pronata and has spun off its DMAT platform—a multiplex system used to detect protein and nucleic acid biomarkers—to the new entity, called MyCartis. The new venture also completed a financing round, raising €15 million. Biocartis CFO Hilde Windels said, "We believe this major fundraising demonstrates the support for Biocartis' ambition to make personalized medicine a truly sustainable, everyday practice. By intensifying the development of our assay menu, we intend to demonstrate the potential of Idylla in the fields of oncology, infectious diseases, and beyond." *See GenomeWeb*, September 4, 2014.

## INVESTOR NEWS

### International Funding Agencies to Support Infectious Disease Research

Under the Ecology and Evolution of Infectious Diseases program, three U.S. agencies—the National Institutes of Health (NIH), National Science Foundation and U.S. Department of Agriculture—joined by U.K. and Israeli partners, will **provide** up to $12 million in 2015 for multidisciplinary research into infectious disease pathogens. The program will support research that uses genomics and other methods to understand how these pathogens are transmitted and the ways they evolve. Funding will be provided to nine award winners, both U.S.- and foreign-based, and proposals are sought in areas such as the interactions between pathogenic and non-pathogenic organisms and their hosts; how medical, agricultural or environmental practices affect pathogen emergence and transmission; host switching; and evolutionary dynamics in an ecological context. The deadline for submissions to NIH is November 19, 2014. *See GenomeWeb*, August 21, 2014.

### Stem Cell Company Files $90-Million Shelf Registration

Madison, Wisconsin-based Cellular Dynamics International, Inc. has **filed** a "shelf registration" with the U.S. Securities and Exchange Commission indicating its intent to offer shares of common and preferred stock, and other securities combinations from time to time for up to $90 million. When the company went public in 2013, it raised $43 million; with its shelf registration, the company will be able to offer and sell securities without a separate prospectus for each offering. The company focuses on human induced-pluripotent stem-cell technologies to produce cell types in the industrial quantities needed for basic life-science and drug-discovery research.

### NanoString Technologies Seeks Up to $100 Million in Shelf-Registration Filing

A molecular diagnostics and genetic analysis products company has **filed** a $100-million "shelf registration" with the U.S. Securities and Exchange Commission. Seattle, Washington-based NanoString Technologies, Inc. will offer common stock, preferred stock and other securities offerings from time to time to raise funds for general corporate purposes. This type of filing allows certain issuers to offer securities to the public without a separate prospectus for each offering. At the time of filing, the company had some 18 million shares of common stock outstanding. The company's products are based on digital molecular barcoding technology. In 2013, it launched Prosigna™, its first *in vitro* diagnostic product for early stage breast cancer in Europe and Israel.

**Virginia Biotech Raises $3.5 Million to Support Brain-Cancer Therapeutics**

Diffusion Pharmaceuticals LLC has indicated in a U.S. Securities and Exchange Commission filing that it has raised $3.5 million. According to a news source, the company, which is headquartered in Charlottesville, Virginia, is in mid-stage clinical trials at 18 major cancer centers for its lead drug candidate—trans sodium crocetinate. It is apparently being tested with radiation therapy and has been designated an orphan drug for newly diagnosed primary brain cancer and brain metastasis. The company's small-molecule drugs apparently help regulate the movement of oxygen into tissue "to re-oxygenate the microenvironment of solid cancerous tumors," which have diminished oxygen levels. The therapy reportedly enhances the tumor cells' response to conventional treatment without other side effects. *See MedCity News*, September 5, 2014.

**Cancer Biotech Secures $1.8 Million in Series A Financing**

Immunophotonics, Inc., a startup that is developing an immunotherapy for the treatment of late-stage metastatic cancers, has reportedly raised $1.8 million in a Series A funding round from investors including BioGenerator, Cultivation Capital, St. Louis Arch Angels, Billiken Angels, and the Missouri Technology Corp. The St. Louis-based company will use the proceeds to support human clinical trials for inCVAX, a therapeutic cancer vaccine, in Latin America and to file for trials in the United States. The company's vaccine involves a two-injection regimen that evidently teaches a patient's immune system to recognize her cancer as foreign and then eliminate cancerous cells throughout the body by inducing an anti-tumor immune response. *See St. Louis Business Journal*, September 3, 2014.

**Bellicum Pharmaceuticals Raises $55 Million for Cellular Immunotherapies**

According to a news source, Houston, Texas-based Bellicum Pharmaceuticals, Inc. has raised $55 million in an oversubscribed Series C financing round that included 11 new biotech and mutual fund investors. The company focuses on immunotherapies that allow the suppression or activation of cells administered to leukemia, lymphoma or pancreatic cancer patients. Bellicum CEO Tom Farrell said, "With this financing, we're well positioned to accelerate the clinical development of BPX-501 in leukemia/lymphoma and in nonmalignant genetic diseases, and to hit important development milestones with our (CAR) T cell and DeCIDe cancer vaccine programs." *See Bellicum Pharmaceuticals, Inc. Press Release*, August 27, 2014.

## BUSINESS CLIMATE

### Biotech Investments Reach Record Highs in Q2 2014

According to a MoneyTree™ report, venture capitalists (VCs) invested $1.84 billion in 122 biotechnology deals during the second quarter (Q2) of 2014; this was up 69 percent from the previous quarter. Life sciences funding overall increased 47 percent from Q1, rising from $1.7 billion invested to $2.5 billion. Pricewaterhouse Coopers LLP Life Sciences Partner Greg Vlahos said, "The industry's stellar fundraising quarter is due to a virtuous cycle for biotechs. The IPO [initial public offering] boom has provided VCs with some very real exit opportunities, and the public markets' warm reception to drug developers has pushed M&A [mergers and acquisitions] valuations skyward. Combined, those factors have created significant liquidity for investors, allowing VCs to quickly gather new funds and back more companies." Analyzing regional funding trends, the report placed the San Francisco Bay Area in the lead, closing 54 deals during Q2, with an average deal size of $16 million. The other leading regions in order were Boston, San Diego Metro, New York Metro, and Great Lakes.

### KC Animal Health Corridor Claims 56 Percent of Total Worldwide Sales

An asset survey unveiled to animal health industry leaders during recent Kansas City (KC) Animal Health Corridor "homecoming" activities reportedly showed that companies located in the corridor represent 56 percent of all worldwide animal health, diagnostics and pet food sales. According to Corridor Advisory Board Chair Scott Bormann, "This latest survey is a powerful endorsement of nearly a decade of cooperation, teamwork and strategic focus that has driven the activities of the KC Animal Health Corridor effort since 2006." Since that launch, 31 new animal health companies have apparently moved into the corridor, pledging to create more than 1,300 new jobs with $78.6 million in new payroll and making a total $872.5-million capital investment with facilities that occupy in excess of 1 million square feet of new space. More than 300 animal health companies are now headquartered along the corridor which reaches from the west in Manhattan, Kansas, to the east in Columbia, Missouri. *See FierceAnimalHealth*, August 29, 2014.

## LEGISLATIVE AND REGULATORY DEVELOPMENTS

### "Purple Book" Sets Forth Approved Biologicals, Will Expand to Biosimilars

The U.S. Food and Drug Administration (FDA) has **released** lists of reference biological products regulated by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research. The lists, referred to as the "Purple Book," "include the date a biological product was licensed under 351(a) of the PHS [Public Health Service] Act and whether FDA evaluated the biological product for reference product exclusivity under section 351(k)(7) of the PHS Act." This will enable users to determine whether a licensed biological product "has been determined by FDA to be biosimilar to or interchangeable with a reference biological product." When FDA begins to approve biosimilars, they will be included in the Purple Book. *See FDA Purple Book*, September 9, 2014.

### FDA Releases Clinical Trial Action Plan

The U.S. Food and Drug Administration (FDA) has **issued** a 27-point action plan aimed at improving diversity in clinical trials. While the numbers of women participating in clinical trials has been increasing, racial and ethnic minorities apparently continue to be underrepresented. A law passed in 2012 required FDA to "take a closer look at the inclusion and analysis of demographic subgroups in applications for drugs, biologics and devices—including by sex, race and ethnicity, and age—and report" its findings. FDA issued its "Section 907" report to Congress in 2013 and, under the law, was required to complete an action plan one year later.

The 27 actions, many of which will involve collaboration with stakeholders and other government agencies over the next five years, are grouped under three priorities: "improving the completeness and quality of demographic subgroup data collection, reporting and analysis (quality); identifying barriers to subgroup enrollment in clinical trials and employing strategies to encourage greater participation (participation); and making demographic subgroup data more available and transparent (transparency)." Acknowledging that representation of diverse populations is beneficial "in applications for FDA-regulated medical products," the action plan notes, "By improving data quality, encouraging greater participation in clinical trials, and making demographic subgroup data more available and transparent, we can help to ensure that researchers, health professionals and consumers will have easy access to meaningful clinical information about medical products that will help them make informed decisions."

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## LITIGATION

### Vaccine Developer Agrees to Settle Shareholder Litigation

A putative class action instituted by three shareholders against the now-bankrupt biotechnology company Biovest International, Inc., alleging misrepresentations about the performance of a non-Hodgkin's lymphoma treatment vaccine, has apparently settled for $1.25 million. *Hill v. Accentia Biopharmaceuticals, Inc.*, No. 13-1945 (U.S. Dist. Ct., M.D. Fla., unopposed motion for preliminary approval filed September 5, 2014). The plaintiffs alleged that the Accentia Biopharmaceuticals Inc. subsidiary and its board of directors violated federal securities laws by issuing false and misleading press statements indicating that its BiovaxID vaccine succeeded in a key clinical trial and that it intended to seek approval for it in the United States and internationally. When the truth about the trial was revealed, i.e., federal regulators had determined that the data sets were not sufficient to support a biologics license application and required a plan for additional research that was never carried out, Biovest shares reportedly lost 70 percent of their value and the company filed for bankruptcy protection. The motion for preliminary approval of the settlement seeks to certify all those who held Accentia or Biovest shares from July 2008 through August 2012. *See Law360*, September 5, 2014.

## NEWS BYTES

The U.S. Patent and Trademark Office (USPTO) **seeks** comments on the estimated time burdens of revisions to a currently approved information collection involving the credentials and qualifications of new or existing practitioners on its Register of Patent Attorneys and Agents. USPTO anticipates that it will take some 21,800 respondents each year three minutes to 40 hours to prepare the appropriate forms and submit them. The information is used to determine whether the applicant "is of good moral character and repute; has the necessary legal, scientific, and technical qualifications; and is otherwise competent to advise and assist applicants in the presentation and prosecution of patent applications." Comments are requested by October 8, 2014.

The U.S. Food and Drug Administration **requests** comments on proposed draft guidance that addresses issues related to the development of drugs for Duchenne muscular dystrophy (DMD). The draft guidance was submitted to the agency in June 2014 by stakeholders in the DMD community, including Parent Project Muscular Dystrophy. The deadline for submissions is October 6, 2014.

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The U.S. Food and Drug Administration (FDA) **requests** comments on changes to the estimated time burdens for a collection of information following its review of comments on draft guidance for industry titled "Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Drug products compounded in an outsourcing facility can qualify for exemptions from FDA approval requirements and certain labeling requirements, and those facilities electing to register must submit certain information to the agency. FDA revised the time burdens in response to comments on the draft guidance relating to the information collection, increasing its estimates of the number of outsourcing facilities that will be subject to the guidance. Comments are requested by September 26, 2014.

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## 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.

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