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BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
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PHARMACEUTICAL

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IP NEWS

Europe Sees Strong Growth in Biotech Patent Filings

According to a news source, biotechnology patent applications filed with the European Patent Organization (EPO) grew more than 42 percent in 2010 from the previous year. Overall, EPO patent filings increased 11 percent, with 235,000 filed in 2010. EPO President Benoit Battistelli reportedly said, "In 2010 there was an increase in demand for patent protection from every region of the world. After a two-year slump, the EU and US are clearly back to their levels of patenting [since] before the crisis. This combined with a massive rise in patent applications from Asia—led by China—has made 2010 a record year at the EPO." The United States and Japan apparently led the countries of origin at 26 percent and 18 percent of total applications, respectively. *See EPO News Release*, April 13, 2011.

NEW BIO BUSINESS VENTURES

Biotechs Launch Stem Cell Research Joint Venture

California-based BioTime Inc. and XenneX Inc. have announced a joint venture to "develop and commercialize a database of the thousands of cell lineages branching from embryonic stem cells and their molecular markers." Called LifeMap Sciences, the joint venture will allow stem cell researchers at pharmaceutical and biotechnology companies and institutions to follow the development of embryonic stem cell lines "to the purified progenitor cell lines" created through BioTime's ACTCelerate™ technology. Users will pay a subscription or a fee based on use.

XenneX, with worldwide operations in Massachusetts, Israel and China, offers GeneCards®, a "relational database for information on each of thousands of genes in human DNA" used by medical researchers. "The opportunity to develop a platform for stem and progenitor cells is one we could not let pass," said company chair David Warshawsky. "The aging baby boom population and rising costs of health care make cost-effective therapies in age-related diseases a near-term necessity. Stem and progenitor cells lines are instru-

mental in helping researchers develop therapeutics for these diseases. We aim to give them one place to find all the information they need to determine which cells they need for their research and the cell-related information necessary to develop life-saving cures in the future." *See BioTime Press Release,* April 5, 2011.

Joint Venture to Create Algae for Biofuels

Bard Holding Inc. and Algae Bioenergy Solutions (ABS) have announced a joint venture to develop an algae production facility in Augusta, Georgia. Bard-ABS Inc. will apparently develop the site to accommodate a "10-million gallon—expandable to 100 million gallons per year capacity of algae oil production." The venture will also provide feedstock for ABS's biodiesel production, "as well as valuable co-products."

According to ABS, "Bard's modular, highly scalable system of Photo BioReactors (PBRs) will utilize its proprietary process to cultivate algae on an unprecedented commercial scale. In this process, algae is grown at rapid rates under artificial lighting. The high-density oil is extracted and can be converted into jet-fuel, green diesel, biodiesel, bioplastics, cosmetics, as well as used in numerous products in the nutraceutical and pharmaceutical markets."

Targeted for completion by January 2012, the algae facility will be built in an existing 200,000 square-foot facility owned by ABS. All crude algae oil produced will be sold to Green Valley Biofuels, an ABS sister company, and "co-products will be sold to the food, health, fish food industries." Initial funding will be raised by a project portfolio management of $10 million. *See ABS Press Release,* April 6, 2011.

INVESTOR NEWS

Chinese Billionaire Backs U.S./China Biopharma Venture

Chinese real-estate billionaire Qi Jinzing has reportedly begun investing in the biotech sector despite its potential financial risks. He was quoted as saying, "I believe the investment in biotech has benefits beyond financial rewards, like reducing suffering in patients." Qi has apparently backed a company that will operate in the United States and China to develop cancer and anti-infective drugs. The new company, Ascletis, plans to license promising compounds from U.S. and European companies for development and marketing in China. The venture is believed to be the first Chinese investor-backed initiative to operate in both the United States and China. Asked to compare what could ultimately be a philanthropic venture with the work of another billionaire, Qi said, "I share the same dreams as Bill Gates, but I am not as rich as him." *See Forbes.com*, April 6, 2011.

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Michigan LifeScience Venture Fund Raises $15 Million

SWMF (Southwest Michigan First) LifeScience Venture Fund has reportedly raised $15 million to invest in life sciences companies with major operations in southwest Michigan, particularly around Kalamazoo. Pat Morand, the fund's managing director, told a news source that the goal is to raise another $35 million. According to its **Website**, the fund has invested in seven companies to date. *See MedCity News,* April 13, 2011.

Pressure BioSciences Receives First Portion of $6 Million Private Placement

Pressure BioSciences Inc. (PBI) has announced "gross proceeds of $825,720 from the sale of 55,048 units to 10 accredited investors, including the company's CEO and president, in the first tranche of the company's $6 million Series C private placement." Focused on making instruments to take samples of proteins, DNA, RNA, and small molecules for biological research, the Massachusetts-based life sciences company said each unit, sold at $15, consisted of one share of Series C convertible preferred stock and one warrant to buy 10 shares of common stock at $2.38 per share, expiring April 2014. *See PBI Press Release* and *Mass High Tech,* April 13, 2011.

BUSINESS CLIMATE

Study Claims Algae Could Replace 17 Percent of U.S. Oil Imports by 2022

The Department of Energy's Pacific Northwest National Laboratory (PNNL) has released a study claiming that algae-derived oils could replace 17 percent of the nation's imported oil by 2022. Mark Wigmosta, et al., "National microalgae biofuel production potential and resource demand," *Water Resources Research,* April 13, 2011. "Algae has been a hot topic of biofuel discussions recently, but no one has taken such a detailed look at how much America could make—and how much water and land it would require-until now," lead author and PNNL hydrologist Mark Wigmosta said. "Algae could be part of the solution to the nation's energy puzzle—if we're smart about where we place growth ponds and the technical challenges to achieving commercial-scale algal biofuel production are met."

Researchers factored in how much water would need to be replaced due to evaporation over 30 years and "analyzed previously published data to determine how much algae can grow in open, outdoor ponds of fresh water while using current technologies." Concluding that "water use could be drastically cut if algae is grown in the sunniest and most humid climates: the Gulf Coast, the Southeastern Seaboard and the Great Lakes," researchers estimated that the amount of land needed to produce the algae would be roughly the size of South Carolina. They also determined that "21 billion gallons of algal oil, equal to the 2022 advanced biofuels goal set out by the Energy Independence and

Security Act, can be produced with American-grown algae." *See PNNL Press Release,* April 13, 2011.

In a related development, photosynthetic bacteria called cyanobacteria may reportedly provide promise in the advancement of algae fuels. Cyanobacteria, which "used to be known as blue-green algae—just another kind of pond scum," do not store oily fats in their cells like microalgae. Evidently, many varieties can easily integrate foreign DNA, making them "ideal fuel candidates," some microbiologists believe. *See Greenwire,* March 29, 2011.

Mergers Affect Boston Biotech Independence

Biotech company executives meeting recently in Boston, were reportedly concerned about the growing buy-out trend among area businesses. While small, underfunded companies and venture-backed start-ups welcome the infusion of cash provided by a large, single company takeover, others would apparently prefer funding by a number of institutional and individual investors. The CEO of Alkermes Inc., which is marketing a drug that treats alcohol and opioid dependence, was quoted as saying, "It's a big concern. But there's not a hell of a lot you can do about it except to make yourself look unattractive." According to CEO Matthew Emmens of Vertex Pharmaceuticals, Inc., "It's not going to be your decision. It's going to be the shareholders' decision. Somebody either comes up and writes you a check, or they don't." The trend is apparently attributed to the regulatory environment, described as "unforgiving," and the dearth of new drugs coming out of the world's largest pharmaceutical companies. *See The Boston Globe*, April 13, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

House Advances Patent Reform Legislation

The House Judiciary Committee has approved legislation (H.R. 1249) that would reform the nation's patent system. The House version of the "American Invents Act" was reported favorably to the floor by a 32-3 vote; it is still pending before the House Budget Committee. According to a committee news release, the bill incorporates many of the reforms already approved by the Senate. Among other matters, the bill would adopt a first-to-file rule, establish a post-grant review process that would allow disputes over patent quality and scope to be settled, authorize a special *ex parte* re-examination of business-method patents, and provide the U.S. Patent & Trademark Office with authority to establish fees to recover the costs of services.

Judiciary Committee Chair Lamar Smith (R-Texas) said when opening the mark-up hearing, "The current patent system is outdated and dragged down by frivolous lawsuits and uncertainty regarding patent ownership. . . . This bill

not only protects small businesses and independent inventors, it creates jobs and even helps bring manufacturing jobs back to the United States." During the hearing, the legislation was amended with a "Manager's Amendment" that, among other matters, was intended to fix an apparent problem with proposed statutory language relating to the "first-to-file rule." According to University of San Diego School of Law Assistant Professor Ted Sichelman, the Senate bill and original House bill do not "effectuate Congress's intent to keep the inventor grace period intact." And the amendment, said Sichelman, "would effectively overrule many years of well-established judicial precedent that non-informing uses and sales by inventors and third parties, as well as a secret use of a claimed method by an inventor to manufacture products then sold to the public, count as bars to patenting."

Sichelman suggested instead that "the provisions enumerating prior art should be left intact, and the exclusionary clause revised to make it absolutely clear that all inventor sales, uses, or other activities that make the invention available to the public less than one year before filing would be excluded as prior art." Otherwise, the amended House bill "would allow inventors to commercially benefit from their inventions (without disclosing them) for an indefinite period of time before filing for a patent." *See Patently-O*, April 12, 2011; *Judiciary Committee Press Release*, April 14, 2011.

New Jersey Lawmaker Proposes Legislation to Aid Small Businesses, Biotechs

U.S. Representative Rush Holt (D-N.J.) recently met with some of the state's biotechnology leaders to discuss his proposed legislation aimed at fostering job creation and providing tax relief to small businesses, including biotech startups. The "Creating Jobs From Innovative Small Businesses Act" (H.R. 4769) would establish a temporary 20 percent tax credit for start-up small businesses that invest 50 percent of their budgets in research. The "Create Jobs by Expanding the R&D Tax Credit Act" (H.R. 132) would temporarily "boost the most common form" of the federal research and development (R&D) tax credit to allow businesses to invest in innovation and hire new workers. Another bill (H.R. 134) would make the R&D tax credit permanent.

"These three bills are not only critical for New Jersey's economy," Holt said. "They would also help invigorate investment in private sector innovation so that we can expand our global leadership in high technology, spur greater economic growth domestically, and remain a leader in technological innovation." *See Representative Rush Holt Press Release,* April 5, 2011.

USPTO to Revise Patent Term Extension and Adjustment Provisions

The U.S. Patent & Trademark Office (USPT)) has issued a notice of proposed rulemaking that would revise "the patent term adjustment and extension provisions of the rules of practice in patent cases." The American Inventors

Protection Act of 1999 and Uruguay Round of Agreements Act "each provide for patent term extension or adjustment if the issuance of the patent was delayed due to appellate review by the Board of Patent Appeals and Interferences (BPAI) or by a Federal court and the patent was issued pursuant to or under a decision in the review reversing an adverse determination of patentability."

Among other matters, USPTO "is proposing to change the rules of practice to indicate that in most circumstances an examiner reopening prosecution of the application after a notice of appeal has been filed will be considered a decision in the review reversing an adverse determination of patentability for purposes of patent term adjustment or extension purposes." In these situations, "patentees would be entitled to patent term extension or adjustment." Public comments are requested by May 6, 2011; no public hearing will be held on the proposal.

FDA Draft Guidance Addresses Safety Labeling Changes

The Food and Drug Administration (FDA) has made available a **draft guidance** titled "Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act," that would provide information on new statutory provisions authorizing the agency "to require certain drug and biological product application holders to make safety related labeling changes based upon new safety information that becomes available after the drug or biological product is approved." Comments on the draft are requested by July 12, 2011.

The **draft** sets out how the agency will implement its authority, "including a description of the types of safety labeling changes that ordinarily might be required under the new legislation, how FDA plans to determine what constitutes new safety information, the procedures involved in requiring safety labeling changes, and enforcement of the requirements for safety labeling changes." Before Congress changed the law, FDA learned about the potential for serious risks from a variety of sources and requested that product application holders make labeling changes. "In most cases, application holders responded to these requests by negotiating appropriate language with FDA staff to address the concerns, and then submitting a supplement or amended supplement to obtain approval of the changes." According to the agency, the process was often protracted, and FDA "had few tools available at its disposal to end negotiations and require the changes."

LITIGATION

Control at Issue in Split Federal Circuit Ruling on Joint Infringement

A divided Federal Circuit Court of Appeals panel, relying on recent precedent, has confirmed that "where the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed only if one party exercises 'control or direction' over the entire process such that every step is attributable to the controlling party.'" ***McKesson Techs. Inc. v. Epic Sys. Corp.*, No. 2010-1291 (Fed. Cir., decided April 12, 2011)**. The control standard "'is satisfied in situations where the law would traditionally hold the accused direct infringer vicariously liable for the acts committed by another party that are required to complete performance of a claimed method.'"

The patent at issue involved "an electronic method of communication between healthcare providers and patients involving personalized web pages for doctors and their patients." The defendant is a software development company that licenses software to health care providers, including a product called "MyChart" that "allows healthcare providers to associate medical records with a patient's personalized web page." It also "allows the patients to communicate with their healthcare provider online through these personalized MyChart web pages." According to the defendant, because the first step of the method, "initiating communication," is not directly performed by the defendant's customers, nor does the company "exercise control or direction over another who performs this step," the plaintiff failed to demonstrate that a single party directly infringes the patent and thus could not succeed on its indirect infringement claim. The district court and Federal Circuit agreed.

A concurring judge conceded that the decision was correct given existing precedent, but questioned the validity of the cited decisions and suggested that they "may warrant review by the en banc court in an appropriate case." The dissenting judge complained that the court "again selectively applies some newly minted panel rulings while ignoring others, adding to the conflict with precedent." She contended that this approach would render "all such interactive methods open for infringement without redress" and also noted that other circuit panels and the U.S. Supreme Court "have held that there can be infringement liability when steps of the claimed method are performed by different entities."

Biotech Company Settles Claims That Counsel Divulged Confidential Information

A federal court in California has dismissed with prejudice claims that a biotech company filed against its former counsel alleging that the law firm had provided confidential information about the company's patent applications to another client. *Tethys Bioscience, Inc. v. Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.*, No. 09-05115 (U.S. Dist. Ct., N.D. Cal., Oakland Div., decided

April 15, 2011). The order was entered on the parties' stipulated dismissal. The patent apparently involved the identification of biological markers for diabetes, and the plaintiff asserted that the similarities between its October 2006 patent application and a nearly identical application the law firm filed on the other client's behalf in March 2007 showed that improper disclosure had occurred.

Prior court orders apparently narrowed the case by dismissing a conversion claim but allowing the plaintiff to proceed with a claim for breach of fiduciary duty. In late 2009, the court reportedly granted the defendant's motion to dismiss, but gave the plaintiff the opportunity to amend the complaint. No additional details about the settlement are available. *See Law360*, April 15, 2011.

NEWS BYTES

The International Service for the Acquisition of Agri-Biotech Applications SEAsia Center launches a **database** of biotech/genetically modified crops and traits that have been approved for commercialization and planting, and for import for food and feed.

The U.S. Patent & Trademark Office (USPTO) **requests** nominations for three members to its Patent Public Advisory Committee and its Trademark Public Advisory Committee.

USPTO **updates** it registration exam for patent practitioners to "help ensure that newly registered patent attorneys and agents are fully qualified in the most current patent laws, rules and procedures."

U.S. and U.K. governments **highlight** progress on a March 2010 joint action plan targeted to "combat the problem of patent backlogs and their effects on the economy and job creation."

UPCOMING CONFERENCES AND SEMINARS

The American Intellectual Property Law Association has **announced** a spring meeting to discuss the latest issues and trends in intellectual property (IP) law. Agenda items for the May 12-14, 2011, meeting in San Francisco, California, include patent damages, new U.S. Patent & Trademark Office rules, inequitable conduct issues facing prosecutors, best practices for in-house trademark lawyers, infringement litigation, patent licensing strategies, global IP enforcement challenges, protecting trade secrets, IP assets and bankruptcy, and "the inside scoop from corporate in-house counsel."

The American National Standards Institute (ANSI) has **scheduled** a May 12, 2011, workshop to consider whether private standards-development organi-

zations have created too many standards, what compels them to do so and how companies, organizations and government agencies can choose from among duplicative or conflicting standards to best meet their needs. Titled "Standards Wars: Myth or Reality?," this workshop will be held in Washington, D.C.; the registration deadline is April 27. ANSI coordinates the U.S. standards and conformity assessment system, accredits standards-development bodies and ensures that standards are created through an open process.

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BIOTECH LEGAL BULLETIN

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