Shook, Hardy & Bacon L.L.P.

ISSUE 56 | MAY 2, 2013

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Genetic Technologies Settles Infringement Suit over Non-DNA Coding Technology

Genetic Technologies Ltd. (GTG) has reportedly settled a patent infringement lawsuit filed in late 2012 against PreventionGenetics. While the terms of the agreement are confidential, the companies have also apparently entered a licensing agreement. According to a news source, the litigation was just one of a number of suits filed by Australia-based GTG to protect U.S. Patent No. 5,612,179, covering its non-DNA coding technology.

The company has also announced that the U.S. Patent and Trademark Office, which in March 2013 reaffirmed the validity of certain claims in the patent, has granted a second re-examination of the patent filed by Merial L.L.C., a defendant in an action GTG filed in May 2011. Noting that such re-examinations are a commonly employed, patent-infringement defense strategy and that "the '179 patent has prevailed in numerous litigation filings in the USA, resulting in positive outcomes in all instances," the company indicates that its current actions may be delayed if the courts decide to stay the matters pending the re-examination process. *See GTS ASC Announcement,* April 19 and 29, 2013; *GenomeWeb*, April 29, 2013.

JOINT VENTURES

Biopharmaceuticals to Collaborate on Cancer Drug Discovery

FORMA Therapeutics Holdings, LLC has reportedly entered a strategic collaboration agreement with Celgene Corp. to discover, develop and commercialize cancer therapeutics. The agreement will focus on drugs that can regulate protein homeostatis targets, and incentives will be provided to FORMA for research and early development of multiple drug candidates, while Celgene will have the right to exclusive licenses on their development and commercialization outside the United States.

According to FORMA Chief Scientific Officer Kenneth Blair, "protein homeostasis represents a new area of promising drug development after years of

targeting kinase family proteins. This significant drug development collaboration has the potential to bring new drugs against novel targets and address unmet medical needs in the treatment of many cancers." CEO Steven Tregay said, "This collaboration provides the long-term commitment and resources to enable FORMA to execute on its vision to build an integrated company bringing transformative cancer therapies to patients in need."

Celgene Senior Vice President George Glumbeski echoed their enthusiasm and said of the collaboration that it "is consistent with our corporate R&D strategy, engaging in large collaborations with leading companies working in emerging areas of biology." Protein homeostasis is apparently viewed as important not only in oncology, but also in neurodegenerative and other disorders. Discovering how it works is expected to "contribute to the understanding of diseases associated with excessive protein misfolding, aggregation and degradation." *See The Wall Street Journal*, April 29, 2013.

Pfenex and Agila Biotech Agree to Develop Biosimilars for Global Market

Bangalore-based Agila Biotech Private Limited has reportedly entered a joint venture with San Diego-based Pfenex Inc. to develop biosimilar products for the global marketplace. The agreement's lead product is multiple sclerosis therapeutic Interferon beta-1b, which is expected to begin human clinical trials by the fourth quarter of 2013. Relying on Pfenex's expertise in strain engineering and process development as well as Agila Biotech's biologics manufacturing and clinical development strengths, the companies are focusing on the development, manufacture and commercialization of an initial pipeline of six biosimilars. The companies will equally share decision-making, and manufacturing will take place in a state-of-the-art facility under construction in Nusajay, Johor, Malaysia.

Pfenex CEO Bertrand Liang said, "Biosimilars are and will play an increasingly important role in patient disease management. This venture between Pfenex and Agila Biotech will allow us to leverage our infrastructure for the development of safe, reliable and cost-effective therapies for patients to address unmet medical needs all over the world." Calling the partnership "creative," Agila Biotech CEO Anand Iyer said that it would "allow us to not only leverage time and cost advantage of developing products in India and Malaysia but also serve as a gateway to a vast region in South Asia, South-East Asia and the OIC [Organisation of Islamic Cooperation] region currently underserved as a result of the lack of high quality, cost-effective biologics." *See Pfenex Inc. News Release*, April 16, 2013.

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.

For additional information on SHB's Life Sciences and Biotechnology capabilities, please contact

John Garretson
Intellectual Property
816-559-2539
jgarretson@shb.com

Patrick Henderson
Corporate Transactions
816-559-2115
phenderson@shb.com

Chris Johnson
Life Sciences & Biotechnology
415-544-1900
cjohnson@shb.com

Madeleine McDonough
Pharmaceutical & Medical Device
202-783-8400
mmcdonough@shb.com

Thomas Moga
Intellectual Property
202-639-5622
tmoga@shb.com

If you have questions about this issue of the Report, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

INVESTOR NEWS

Michigan Biotech Raises $33 Million for Clinical Trials of Small Molecule Therapies

Ann Arbor-based Esperion Therapeutics, Inc. has reportedly completed a $33-million preferred stock financing that CEO Tim Mayleben said will allow the clinical-stage biopharmaceutical company "to continue to advance our novel lead product candidate, ETC-1002, for which we have 100 percent worldwide rights, in multiple ongoing and planned Phase 2 clinical trials." Esperion is developing small molecule therapies for statin-intolerant patients with elevated levels of low-density lipoprotein cholesterol (LDL-C). ETC-1002, an oral LDL-C lowering medication taken once daily, has apparently "been well tolerated and not associated with serious side effects." *See Esperion Therapeutics Press Release*, April 26, 2013.

German Molecular Diagnostics Manufacturer Raises $16.3. Million

Curetis AG, a German molecular diagnostics company, has reportedly raised $16.3 million in a Series B financing round led by new investor HBM Partners AG, bringing the amount of total equity capital raised since inception to $64.07 million. Curetis reports that it intends to use the proceeds "for the next phase of commercial and operational growth" of its CE-marked Unyvero™ System, a hardware platform that can allegedly "detect a broad panel of bacteria and antibiotic resistances from a single sample in one run." Plans include "a prospective, multi-center FDA registrational trial with 2,000 patients," and further expansion of the company's commercial activities and team in Europe.

"We are extremely pleased to have won HBM Partners as lead investor for our new round, said Curetis CEO Oliver Schacht. "With HBM joining our syndicate of investors, we are well positioned to continue executing on our clinical and commercial plans. Our syndicate has the breadth, depth and quality as well as financial strength to take Curetis all the way to achieve its strategic corporate objectives and to globally roll out Unyvero in the years ahead." *See Curetis AG News Release,* April 22, 2013.

Pharmaceutical Trade Group Reports 241 Blood Cancer Drugs in Development

The Pharmaceutical Research and Manufacturers of America (PhRMA) has released a **report** showing that U.S. biopharmaceutical companies have more than 240 medicines in development for the treatment of leukemia, lymphoma and multiple myeloma. The report provides details on each of the medicines, including sponsor, indication and development phase. Noting that more than 100,000 new cases of blood, bone marrow and lymph node cancers are diagnosed in the United States annually, PhRMA points to the "significant

progress in biopharmaceutical research and development" that has achieved "steady improvements in cancer survivorship rates." *See PhRMA News Release*, April 25, 2013.

BUSINESS CLIMATE

Annual Report Reveals Need for Biotech Shift in Focus to Demonstrate Drug Value

According to Ernst & Young's 27th annual biotechnology industry report, the global biotechnology industry has continued its recovery, but small and mid-size companies have apparently been unable to gather the evidence needed to demonstrate the value of their products while they are under development thus hindering the companies' future ability to "raise capital, obtain attractive deal valuations and be successfully reimbursed for their drugs upon approval." Ernst & Young Global Life Sciences Leader Glen Giovannetti said, "In today's increasingly outcomes-focused, evidence-driven health care systems, biotech companies cannot afford to pursue an R&D strategy that only focuses on whether or not their drug works. They need to also understand whether it will be valued and reimbursed by payers."

The report showed that the industry's established biotech centers in the United States, Europe, Canada, and Australia increased their revenues by 8 percent from 2011. Research and development spending apparently slowed, growing just 5 percent in 2012 compared to 8 percent in 2011. Net income reached a record high of US$5.2 billion, which exceeded the previous year's net by US$1.4 billion. Venture funding continued to decrease, but remains resilient, according to the report.

Because smaller biotech companies are focusing on efficiency initiatives far more often than on "measures to collect evidence to demonstrate product value," Giovannetti said, "It's time for biotech firms to debunk any myths that may be holding them back. The shift to evidence is happening faster than many might have expected, and it affects companies regardless of their size, maturity or disease focus. Many evidence-focused initiatives—engaging stakeholders earlier on issues of value and reimbursement, rethinking trial design or exploring pre-competitive data collaborations—don't cost much and could even avoid the expense of additional studies. The question is not whether you can afford to do this, but whether you can afford not to." *See Ernst & Young Press Release*, April 23, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

U.S. Senators Propose Subjecting Compounded Drugs to Federal Regulation

Bipartisan Senate health committee leaders have released **draft** legislation that would give the Food and Drug Administration (FDA) greater oversight of compounding pharmacies, in response to last year's fatal meningitis outbreak allegedly caused by a contaminated compounded drug. The proposal would subject large compounding operations to direct federal oversight by FDA, rather than the state pharmacy boards that have traditionally overseen them.

According to a Senate Committee on Health, Education, Labor, and Pensions one-pager on the discussion draft, the legislation (i) "establishes a clear boundary between traditional compounders and compounding manufacturers"; (ii) "clarifies that compounded drugs are new drugs subject to the Federal Food, Drug, and Cosmetic Act, and specifies which provisions of the law will apply to traditional compounders, and which will apply to compounding manufacturers"; (iii) defines FDA's role in the oversight of compounding manufacturers; (iv) "enhances bulk chemical requirements for the used in all compounded products"; and (v) "encourages communication among states and increases communication between states and the FDA."

House Appropriators Concerned About Sequestration of FDA User Fees

Food and Drug Administration (FDA) Commissioner Margaret Hamburg reportedly testified before a House appropriations subcommittee about the effects of the across-the-board cuts imposed on the federal government and its agencies under the budgetary impasse known as the "sequester," and said that the user fees collected from industry are also subject to sequestration. During the April 26, 2013, hearing, Hamburg indicated that the agency would be unable to spend all of the money without congressional authorization. The fees were apparently negotiated in exchange for FDA's agreement to meet certain performance targets, and Hamburg said, "We aren't going to be able to fully achieve the goals and performance targets." She specifically cited guidance documents, timely new drug and device application reviews, staffing, and user fee programs as at-risk initiatives. Some $320 million in user fees and federal funding are reportedly affected by sequestration, and House member from both parties are evidently concerned about possible delays in the approval of life-saving medicines. *See CQ HealthBeat News* and *Law360*, April 26, 2013.

NASA Tests Plant-Based Biofuel in Jets

National Aeronautics and Space Administration (NASA) researchers recently concluded a series of test flights in California to study the effects of alternate biofuel on "engine performance, emissions and aircraft-generated contrails at altitudes typically flown by commercial airliners."

According to a NASA news release, the experiment involved flying a DC-8 airplane as high as 39,000 feet while an instrumented HU-25C Guardian aircraft followed at distances ranging from 300 feet to more than 10 miles measuring "exhaust composition and contrail characteristics depending on fuel type, plume duration and atmospheric conditions." During the flights, the plane's four engines were powered by "conventional JP-8 jet fuel, or a 50-50 blend of JP-8 and an alternative fuel of hydroprocessed esters and fatty acids produced from camelina plant oil."

The researchers reportedly found that (i) the camelina mixture burned cleaner than standard fuel; (ii) the pilots reported no difference in the plane's performance; and (iii) the pilots noticed a greater improvement in emissions—particularly in soot reduction—when the plane was idling on the ground. Senior research scientist Bruce Anderson from NASA's Langley Research center said, "Producing biofuels for aircraft is still an evolving technology, and for now labor-intensive and thus more costly. Camelina biofuel, for instance, cost about $18 a gallon, while regular fuel runs about $4 a gallon."

NASA will share this research with aircraft manufacturers and plans another phase of its Alternative Fuel Effects on Contrails and Cruise Emissions experiments next year. *See NASA News Release,* April 23, 2013; *Dailypress.com,* April 25, 2013.

LITIGATION

Federal Circuit Addresses Pleading Standards for Patent Infringement Claims

The Federal Circuit Court of Appeals has determined that a federal district court erred by relying on an incorrect pleading standard in dismissing with prejudice two patent infringement complaints involving digital television signals. ***K-Tech Telecomm., Inc. v. Time Warner Cable, Inc.*, No. 2012-1425 (Fed. Cir., decided April 18, 2013)**. According to the district court, plaintiff K-Tech Telecommunications "failed to allege sufficient factual detail regarding Defendant's accused product and the manner in which it is infringing Plaintiff's patents" and thus "failed to allege facts sufficient to state a plausible claim for patent infringement under the standards articulated in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009)."

The Federal Circuit reiterated its position that a plaintiff's proper use of Form 18 "effectively immunizes a claimant from attack regarding the sufficiency of the pleading." And "to the extent any conflict exists between *Twombly* (and its progeny) and the Forms regarding pleadings requirements, the Forms control." Still, the court did not "seek to create conflict where none exists. A complaint containing just enough information to satisfy a governing form may well be sufficient under *Twombly* and *Iqbal*." Because the district court

required the plaintiff, under the plausibility pleading standard of those two cases, to "preemptively identify and rebut potential non-infringing alternatives to practicing the claims of an asserted patent," the Federal Circuit determined that it erred. "Form 18 includes no indication that a patent holder must prospectively anticipate such noninfringement arguments."

Noting that "Form 18 in no way relaxes the clear principle of [Federal Rule of Civil Procedure 8], that a potential infringer be placed on notice of what activity or device is being accused of infringement," the court found that this plaintiff's proper use of the form satisfied its analytic touchstones—notice and facial plausibility. The court remanded the matter for further proceedings.

Life Tech Shareholder Sues to Stop $13.6 Billion Sale to Thermo Fisher

According to a news source, Life Technologies shareholder Chang Choi has filed a lawsuit on behalf of a class of company shareholders alleging breach of fiduciary duties arising from the planned $13.6-billion sale of the company to Thermo Fisher Scientific. Additional information about the deal appears in Issue **55** of this *Bulletin*. Filed in a California state court, the suit reportedly claims that the proposed sale "is the product of a hopelessly flawed process that is designed to ensure the sale of Life Technologies to Thermo Fisher on terms preferential to defendants and other Life Technologies insiders and to subvert the interests of plaintiff and other public stockholders of the company." Under the deal, Life Tech executives and its board would, according to Choi, receive more than $340 million by selling their "illiquid holdings" and thus "board members are conflicted and serving their own financial interests." *See GenomeWeb*, April 23, 2013.

NEWS BYTES

The National Nanotechnology Coordination Office **schedules** a June 11-12, 2013, public workshop in Washington, D.C., "to obtain input from stakeholders regarding the goals and objectives of an updated U.S. National Nanotechnology Initiative (NNI) Strategic Plan that is currently under development and scheduled for completion by December 2013." Registration is limited; it will open May 1 and close June 3 or when capacity is reached. Comments are requested by May 13.

The U.S. Patent and Trademark Office (USPTO) **invites** public comment on a continuing information collection for which it has estimated time and expense burdens. The collection pertains to information USPTO needs to review when deciding whether to loosen or rescind limitations on the disclosure of information contained in patents and patent applications subject to secrecy orders because they involve inventions deemed by the federal government "to be detrimental to national security." The collection also relates

Shook, Hardy & Bacon L.L.P.

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

ISSUE 56 | MAY 2, 2013

to petitions for a foreign filing license for those seeking to file applications for patents in foreign countries. Comments are requested by June 24, 2013.

The Food and Drug Administration (FDA) **issues** draft guidance titled "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.'" The document is intended to help industry prepare premarket applications, humanitarian device exemptions, investigational device applications, premarket notifications, and "de novo requests for medical devices that come into contact with the human body in order to determine the potential toxicity resulting from contact of the component materials of the device with the body." Comments are requested by July 22, 2013.

The Food and Drug Administration **makes available** draft guidance for industry titled "Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors." "The draft guidance provides sponsors of new drug applications (NDAs), biologics licensing applications (BLAs), abbreviated new drug applications (ANDAs), and prescription drugs marketed without an approved NDA or ANDA with a set of principles and recommendations for ensuring that critical elements of product container labels and carton labeling are designed to promote safe dispensing, administration, and use of the product to minimize medication errors." Comments are requested by June 24, 2013.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400

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.

SHB is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most challenging national and international product liability and mass tort litigations.