Shook, Hardy & Bacon L.L.P.

ISSUE 39 | AUGUST 2, 2012

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

USPTO Seeks Public Input on First-to-File Implementation Proposals

The U.S. Patent and Trademark Office (USPTO) has issued proposed changes to its rules of practice to implement the new "first inventor to file" patent system adopted under the Leahy-Smith America Invents Act (AIA). Comments are requested by October 5, 2012.

Among other matters, to change the current rules of practice pertaining to the existing "first to invent" patent-filing system, USPTO would add certain definitions to title 37 of the Code of Federal Regulations, as well as provisions "for the submission of affidavits or declarations showing that: (1) A disclosure upon which a claim rejection is based was by the inventor or joint inventor or by a party who obtained the subject matter disclosed directly or indirectly from the inventor or joint inventor; or (2) there was a prior public disclosure by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor." USPTO is also "proposing to provide for the situation in which a U.S. patent or U.S. patent application has a prior art effect as of the filing date of a foreign priority application by requiring that the certified copy of the foreign application be filed within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application."

The proposed changes would also include the elimination of provisions "directed to statutory invention registrations" and the addition of "requirements for nonprovisional applications filed on or after March 16, 2013, that claim the benefit of the filing date of a foreign, provisional, or nonprovisional application filed prior to March 16, 2013."

Public comments are also sought on USPTO's new Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the AIA. According to the agency, "These guidelines will assist Office personnel in, and inform the public of how the Office is, implementing" these new provisions. Comments must be submitted by October 5.

In a related matter, USPTO will host a series of "roadshows" across the country in September to provide information about new final rules adopted under the AIA pertaining to preissuance submissions by third parties. According to a USPTO statement, "The final rules relate to provisions for inventor's oath/declaration, preissuance submission, citation of patent owner statements, supplemental examination, inter partes review, post grant review, and covered business method review." The final rules are expected to be published in the *Federal Register* by August 16 and take effect September 16. Roadshow sessions will be conducted in Minneapolis, Minnesota (9/10); Alexandria, Virginia (9/12); Los Angeles, California (9/14); Denver, Colorado (9/17); Detroit, Michigan (9/20); Atlanta, Georgia (9/24); Houston, Texas (9/26); and New York City, New York (9/28). *See USPTO Press Release*, July 26, 2012.

NEW BIO BUSINESS VENTURES

Australian Biotech to Merge with Hawaiian Sleep Apnea Device Maker

Sydney-based Novogen has reportedly entered a merger agreement with Kai Medical, which develops sleep apnea devices and wireless respiration monitoring technology. Due diligence and shareholder approval are required to finalize the deal. According to Novogen Chair William Rueckert, "The sleep apnea market worldwide is a rapidly growing market with tremendous opportunities for companies like Kai that have a product with distinct performance advantages. There is a clear unmet need for patients with this condition for a convenient and effective therapy." Kai CEO Bob Nakata said that company has received its CE Mark for Kai Apnea, "which is the key regulatory approval needed for sales in most of the world." Novogen Ltd. will apparently be renamed Kai Medical Holdings Ltd. when the merger takes effect. *See Novogen News Release*, July 27, 2012.

GI-Disorder Pharma Companies Agree to Merge

Synergy Pharmaceuticals Inc. and Callisto Pharmaceuticals Inc. have reportedly entered a definitive merger agreement under which outstanding shares of Callisto common stock will be exchanged for Synergy common stock and 22.295 million shares of Synergy held by Callisto will be cancelled. The deal, which is subject to shareholder approval, will reportedly result in Callisto stockholders owning some 38 percent of the combined company "on a pro forma basis" and Synergy stockholders will own the remainder. The transaction is expected to conclude by late October 2012. Both biopharmaceutical companies have been developing drugs to treat gastrointestinal (GI) disorders and diseases. *See Synergy News Release,* July 20, 2012.

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

Gene-Therapy Company Secures $60 Million in Series D Financing

Cambridge, Massachusetts-based bluebirdbio™ has reportedly completed a successful $60-million Series D financing round. New investors Deerfield Partners, RA Capital and Ramius Capital Group, among others, joined existing investors to provide funding for the gene-therapy company to advance its clinical programs "in severe genetic disorders, including childhood cerebral adrenoleukodystrophy, beta-thalassemia and sickle cell disease," according to a company statement. The company focuses on new treatments for diseases "with few or no clinical options" and "uses stem cells harvested from the patient's own bone marrow into which a healthy version of the disease causing gene is inserted." *See bluebirdbio™ News Release*, July 25, 2012.

Buffalo Biotech Reaches Deal with Russia to Advance Stem-Cell Growth Drug

Cleveland BioLabs, Inc. has signed a contract through a Russian subsidiary with the Ministry of Industry and Trade of the Russian Federation to advance the development of a drug, CBLB612, to stimulate stem cell proliferation and mobilization in bone-marrow patients with radiation-induced deficiencies. Worth approximately US$4 million, the agreement will apparently be used by the Buffalo-based biotechnology company to support the completion of preclinical studies, investigational new drug filing and Phase I and II clinical studies. CEO Yakov Kogan said, "This contract enables us to continue our work with CBLB612. We believe our success in securing this type of highly competitive funding is driven by the strength of our science and development capabilities." The company focuses on the development of a pipeline of compounds primarily used in oncology applications and for the mitigation of radiation injury. *See Cleveland BioLabs Press Release*, July 30, 2012.

EU Provides Clinical Research Grants to Oxford Gene Technology

According to a news source, Oxford Gene Technology has been awarded two European Union (EU) clinical research grants totaling US$3.6 million to provide genomic analysis and commercialization services as part of the international studies EUCLIDS and PATHSEEK. EUCLIDS, or the EU Life-Threatening Infectious Disease Study, is a five-year, large-scale study that will apparently identify genomic variants related to children's susceptibility to bacterial infections and their severity. Among other matters, Oxford Gene will conduct whole exome and RNA sequencing, methylation analysis, and microRNA analysis as part of the project. PATHSEEK is a three-year study aimed at demonstrating "the potential of next generation sequencing technologies in clinical microbiology labs, to enable the detection of pathogens directly from clinical samples and the early detection of drug resistant mutations." HIV, mycobacterium tuberculosis, hepatitis B and C, and influenza A are part of

this research project for which the company will apparently have the rights to sell final assay enrichment and sequencing panels to clinical microbiology laboratories. *See Oxford Gene Technology Press Release*, July 24, 2012.

Quasi-Public Massachusetts Agency Seeking Companies for Tax Giveaways

The Massachusetts Life Sciences Center is reportedly offering up to $25 million in tax incentives for companies that will expand or create jobs in the state. Applications are apparently being sought for the fourth round of a program that has granted 57 awards totaling $56.7 million in previous rounds. Intended to promote the commercialization of life-science research, the program requires companies to demonstrate the scientific and economic merit of their expansion plans. Among those that have apparently been awarded tax incentives is Nova Biomedical Corp., which employs some 700 full-time workers in Massachusetts and has used the support for a new manufacturing facility in Billerica.

Center CEO Susan Windham-Bannister said, "Our Tax Incentive Program has provided a solid return on investment for the taxpayers by incentivizing job creation and holding the companies involved accountable for their job creation commitments." The deadline for applications is October 25, 2012. *See Mass. Life Sciences Center Press Release*, July 23, 2012.

BUSINESS CLIMATE

Biotech Investments Can Bring Big Returns; VC Investors Still Shunning Startups

According to a Silicon Valley Bank study, venture capitalists saw significant returns on their investments in life sciences companies in 2011 due to a plethora of "Big Exits," that is, merger and acquisition activity where "the upfront payment totaled in excess of $50 million for device companies and $75 million for biotech companies." The 35 big exits were apparently the highest in seven years, and "while this does not correct the poor overall returns for the last decade, these dynamics position life science as an attractive investment opportunity now and in the future," said the study's author. Up-front returns for investors from these deals totaled $8.8 billion. A number of companies in oncology, diagnostics, orthopedics, anti-infectives, and cardiovascular received significant amounts of capital in the 2005-2007 time frame, positioning them for "continued solid exit activity," which, according to the study, generally occurs between five and eight years from the close of Series A financing.

Some investors are evidently not willing to wait seven or more years for a return, and second quarter (Q2) 2012 data bear that out as both the money invested and the number of deals fell dramatically from the same period in

2011. In Q2 2012, $696.8 million was reportedly invested in 90 biopharmaceutical companies, down from the $1.4 billion in 129 deals during Q2 2011. According to PricewaterhouseCoopers' most recent MoneyTree Report®, venture capital investors are shunning biotech startups. In the last quarter, just $44 million was invested in 14 deals, as compared to $173 million invested in 21 deals in Q2 2011. *See Genetic Engineering & Biotechnology News*, July 23, 2012.

Reuters Flags Biotechs with Potential to Yield Windfall Profits in Takeovers

A recent *Reuters* analysis has found that six U.S. biotechnology companies identified as potential takeover targets were positioned to yield billions of dollars in shareholder profits at current share prices. Among the companies named were Alexion Pharmaceuticals Inc., BioMarin Pharmaceutical Inc., Seattle Genetics Inc., and Vertex Pharmaceuticals Inc.; their ownership is apparently dominated by just a few institutional investors. The analysis, based on investors' stock holding reports, calculated "the average cost, weighted by both the trading volume over each quarter and the shareholders' own transactions over the years." Analysts noted that a company's existing drugs, pipeline, therapeutic need, and an acquirer's strategic needs are also key matters to consider in any deal. *See Reuters*, July 18, 2012.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FDA Ordered to Release Documents in Spy Fracas Linked to Medical Device Approvals

While Senator Chuck Grassley (R-Iowa) has **demanded** information about the individuals who approved the use of software that could monitor the electronic communications of Food and Drug Administration (FDA) scientists who expressed concerns to Congress about the safety of medical devices, a court has ordered the agency to produce documents in related litigation brought by the whistleblowing scientists against the agency. Additional information about FDA's surveillance action and the inadvertent posting of the scientists' personal emails on the Internet appears in "The Final Word" section of the **July 19, 2012**, issue of Shook, Hardy & Bacon's *Product Liability Litigation Report*.

Noting that the scientists do not seek expedited processing of the 80,000 pages of documents that were published on the Internet, a federal court in the District of Columbia has ordered FDA to produce responsive documents not among those already made public by specific dates in August and September 2012. *Nat'l Whistleblower Ctr. v. Dep't of Health & Human Servs.*, No. 10-2120 (U.S. Dist. Ct., D.D.C., order entered July 23, 2012). The court has also scheduled a status conference for September 27.

Meanwhile, *The National Law Journal* has reported that other government agencies, including the Drug Enforcement Administration and U.S. Department of Veterans Affairs also purportedly purchased the software that FDA used to monitor its scientists' computers after they wrote to Congress, lawyers, journalists, and President Barack Obama (D) contending that the agency approved medical imaging devices that allegedly exposed mammogram and colonoscopy patients to unsafe radiation levels. FDA has reportedly claimed that it used the software to ensure that the scientists were not leaking confidential material that contained trade secrets. A spokesperson from Grassley's office has apparently indicated that the senator may widen the scope of his investigation to other agencies. *See The National Law Journal*, July 30, 2012.

EU Regulators Charge Pharma Companies with Antitrust Violations in Pay-for-Delay Deals

The European Commission (EC) has reportedly charged nine pharmaceutical companies with breaches of European Union (EU) antitrust rules for entering pay-for-delay deals with generic competitors. According to a news source, the EC has in recent years increased its scrutiny of settlement agreements in which brand-name companies pay generic drug makers to delay selling their rival products. While the companies vigorously defended their actions and do not believe they are violating European competition law, the EC said that "substantial value transfers" led to abstentions from entering the market and involved direct payments, the purchase and destruction of generic products, or "guaranteed profits in a distribution agreement." *See Reuters*, July 25, 2012.

EU Medicines Agency Approves First Gene Therapy Drug

The European Medicines Agency (EMA) has reportedly recommended the approval of a gene therapy drug, said to be the first in the western world, representing an important advance for this medical technology. The drug maker, a small Dutch biotechnology company, lost its funding in the public marketplace due to three previous rejections by the EMA and was taken private earlier this year. Approval was difficult because the drug, Glybera, could be tested in clinical trials on 27 patients only, given the rarity of the condition for which it was created, a genetic disorder known as lipoprotein lipase deficiency. Patients with this disease are apparently unable to consume a normal diet because fat particles in their blood cannot be processed, leading to acute pancreatic inflammation and death. With the "thin evidence base," EMA conditioned approval on the drug's use for the worst-affected patients who must be followed after receiving the therapy.

While the concept of treating disease by replacing a defective gene with a working copy became viable in 1990, this research field reportedly underwent a number of setbacks when gene therapy patients died or developed serious side effects since then. A gene therapy drug for the treatment of head and

neck cancer was approved in China in 2003, but the European Union and United States have not approved similar products until now. The European Union is expected to accept EMA's recommendation in the next few months, and the drug's developer is planning to apply for regulatory approval in the United States, Canada and other markets. *See Reuters*, July 20, 2012.

LITIGATION

Federal Court Allows FDA to Exercise Authority over Stem Cells

A federal court in the District of Columbia has determined that "the cultured cell product is a drug within the meaning of the Federal Food, Drug, and Cosmetic Act" and "a biological product within the meaning of 42 U.S.C. § 262," and imposed a permanent injunction against a company and several individuals who allegedly manufactured and distributed misbranded and adulterated stem cells. *United States v. Regenerative Sciences, LLC*, No. 1:10-cv-01327-RMC (U.S. Dist. Ct., D.D.C., decided July 23, 2012). The U.S. Food and Drug Administration (FDA) had sought the injunction against Regenerative Sciences, "citing violations of current good manufacturing practice (CGMP) that cause its cultured cell product to be adulterated." FDA also alleged that the product was "misbranded due to the lack of adequate directions for use and the failure to bear the 'Rx only' symbol." *See FDA News Release*, August 6, 2010.

The cultured cell product at issue was "derived from a patient's bone marrow or fluid surrounding the patient's joints (synovial fluid). The cells are grown, processed, and mixed with drug products outside the body before being injected back into the patient."

The court's order gives FDA access to the defendants' facilities without prior notice to monitor and ensure compliance and requires the defendants to reimburse FDA for the costs of all such inspections. The defendants are further required to hire an independent third party to inspect their facilities to "determine whether their methods, facilities, and controls are operated and administered in conformity with CGMP and to evaluate the labeling of Defendants' cultured cell product and any other drugs manufactured, processed, packed, labeled, held, and distributed by Defendants to determine whether they are in compliance with 21 U.S.C. §§ 352(f) and 353(b)(4)." The order does not apply "to drugs that are both (A) the subject of an effective new drug application or biologics license application approved by FDA and (B) not manufactured, processed, packed, or labeled by Defendants."

Federal Courts of Appeals Conflict over Validity of Pay-for-Delay Deals

The Third Circuit Court of Appeals issued a ruling in mid-July that found "any payment from a patent holder to a generic patent challenger who agrees to

delay entry into the market [must be treated by a factfinder] as *prima facie* evidence of an unreasonable restraint of trade," thus supporting the Federal Trade Commission's (FTC's) view that pay-for-delay deals that settle patent disputes between name-brand pharmaceutical companies and their generic drug competitors violate antitrust law. ***In re: K-Dur Antitrust Litig.*, Nos. 10-2077, -2078, -2079, -4571 (3d Cir., decided July 16, 2012)**.

The court specifically rejected contrary rulings adopted in the Second, Eleventh and Federal Circuits, which apply a "scope of the patent" standard under which these agreements are permitted if the exclusion does not exceed the patent's scope, the patent holder's claim of infringement was not objectively baseless, and the patent was not procured by fraud on the U.S. Patent and Trademark Office. The Eleventh Circuit recently declined a request to rehear *en banc* its decision to dismiss the FTC's antitrust challenge to pay-for-delay deals with several generic drug companies. *FTC v. Watson Pharms., Inc.*, No. 10-12729 (11th Cir., decided July 18, 2012). Additional details about the Third Circuit opinion and related rulings, as well as the regulatory context for these matters appear in the **July 2012 issue** of *IpQ*, a newsletter prepared by Shook, Hardy & Bacon Intellectual Property Partner **Peter Strand**.

The New York Times notes that the Third Circuit's decision "potentially sets up a confrontation before the United States Supreme Court," which often bases its decisions to grant review of cases on splits among the circuit courts of appeals. Industry leaders have suggested that the ruling is an anomaly, unlikely to be followed by other courts. A bill that would stop the companies from entering pay-for-delay deals remains stalled in the U.S. Senate despite claims by the Congressional Budget Office that the legislation could reduce drug costs in the United States by $11 billion and save the federal government $4.8 billion over 10 years.

Pharmaceutical companies contend that the settlements are a cost-effective way of resolving patent disputes with generic manufacturers, which also deny that the agreements are collusive. Generic Pharmaceutical Association Chief Executive Ralph Neas was quoted as saying, "These agreements have never delayed the availability of a generic drug past the expiration of a brand-name drug's patent." He noted that, in recent years, generic drugs reduced drug costs in the United States by $931 billion and one-third of the cost savings was a result of patent settlements. *See The New York Times*, July 26, 2012.

Federal Circuit Vacates Contempt Sanctions Against Counsel in Patent Dispute

The Federal Circuit Court of Appeals has determined that a district court in California erred by failing to consider issues of fairness when it (i) determined that pre-litigation disclosure of a letter protected by attorney-client privilege waived discovery beyond the four corners of the letter; and (ii) entered contempt sanctions against the law firm which authored the letter and failed

to comply with discovery orders relating to the letter's subject matter in a patent dispute between the law firm's client and the company to which the letter had been disclosed. ***Wi-LAN, Inc. v. LG Electronics, Inc.*, No. 2011-1626 (Fed. Cir., decided July 13, 2012)**.

The law firm's client, Wi-LAN, had disclosed to LG Electronics a confidential letter containing counsel's analysis of Wi-LAN's patent rights and counsel's opinion that LG Electronics was practicing Wi-LAN's technology and thus owed royalties on its license. According to the court, "Apparently, Wi-LAN hoped that the letter's reasoning would convince LG to revise its position and begin paying royalties." When the letter did not have the desired effect, Wi-LAN sued LG for patent infringement, and LG subpoenaed the law firm, seeking documents and testimony relating to the letter's subject matter. The firm unsuccessfully sought to quash the subpoena, claiming that "fairness does not compel a subject-matter waiver." The firm was also found in contempt for not complying with the district court's discovery orders.

While the Federal Circuit agreed that the letter was privileged and that Wi-LAN's disclosure waived the privilege as to the letter itself, the court concluded that in the Ninth Circuit, where the discovery dispute arose, a fairness balancing test as to the scope of the waiver would likely be applied. Thus, the court remanded the matter for the district court to evaluate "whether LG would be unfairly prejudiced by Wi-LAN's assertion of privilege against discovery into attorney-client communications beyond the four corners" of the letter when assessing the scope of the waiver. The court also vacated the sanctions imposed against the firm for contempt, but did not rule them out, noting that the firm "had options that it did not pursue" when disputing the subpoena's lawful scope.

Sanctions Imposed on Counsel in Patent Litigation Affirmed

The Federal Circuit Court of Appeals has upheld nearly $44,000 in sanctions imposed on the attorney for a plaintiff in patent litigation, finding that he was equally responsible for his client's failure to adequately respond to an interrogatory seeking its infringement theory. ***Rates Tech., Inc. v. Mediatrix Telecom, Inc.*, No. 2011-1384 (Fed. Cir., decided July 26, 2012)**. The disputed patents involved systems for minimizing the cost of placing long-distance telephone calls.

The interrogatory sought the basis for each claim of infringement, "including without limitation, identification on an element-by-element basis of the component, structure, feature, functionality, method or process of each accused Mediatrix product that allegedly satisfies each element." According to the Federal Circuit, the plaintiff failed on four separate occasions to respond to the "contention" interrogatory despite the court's repeated orders that it do so.

On appeal, the plaintiff's counsel argued that he should not be sanctioned for failing to provide information not within his possession and that he did not

Shook, Hardy & Bacon L.L.P.

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

ISSUE 39 | AUGUST 2, 2012

personally violate any discovery orders. The court found that the "thousands of pages of technical drawings and other documents" produced by the defendant in discovery was "substantial" and enabled the plaintiff and counsel "to make an element-by-element claim construction analysis" as requested by the interrogatory. Thus, the court rejected counsel's argument that "sanctioning him for failing to produce information not within his possession violated his due process rights." The court also found that counsel had more than adequate notice that he could be subject to sanctions for failing to comply with the lower court's directives.

NEWS BYTES

The U.S. Patent and Trademark Office (USPTO) publishes a final rule to implement America Invents Act deadlines for the commencement of disciplinary proceedings for misconduct before the USPTO. The complaint must be filed "within one year after the date on which the Office of Enrollment and Discipline Director receives a grievance forming the basis of the complaint, and in no event more than ten years after the date on which the misconduct forming the basis for the proceeding occurred."

The Food and Drug Administration (FDA) issues draft guidance titled "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." According to FDA, the guidance is intended to "describe the Pre-Submission program (formerly the pre-Investigational Device Exemption (IDE) program) for medical devices reviewed in the Center of Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER)." Comments are requested by September 11, 2012.

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.