Shook, Hardy & Bacon L.L.P.

ISSUE 4 | DECEMBER 16, 2010

BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

USPTO Plan to Fast-Track Humanitarian Patent Re-Examination Unsound?

In response to a U.S. Patent and Trademark Office (USPTO) proposal to expedite the re-examination of patents for technologies addressing humanitarian needs, three intellectual property (IP) organizations have apparently filed comments in opposition. The American Intellectual Property Law Association (AIPLA), Biotechnology Industry Organization and Intellectual Property Owners Association reportedly contend that preferential treatment for technologies that treat topical diseases, improve medical diagnoses, lead to more nutritional or higher-yield crops, or treat wastewater would unnecessarily burden USPTO and could violate U.S. patent laws or IP treaties. They also suggest that the proposal could open the system to subjectivity and delays for the re-examination of patents in other fields as well as unfairness and a lack of predictability.

The agency's "Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System," 75 Fed. Reg. 57,261 (9/20/10), proposed a pilot program under which "patent holders who disseminate their patented technologies for humanitarian purposes would qualify for a fast-track *ex parte* re-examination voucher" that would allow "a patent owner to affirm the validity of his or her patent more quickly and less expensively." Re-examination is apparently done at the request of patent owners and third parties, seeking to affirm or challenge a patent's validity. According to Under Secretary of Commerce and USPTO Director David Kappos, "A voucher for fast-track re-examination of a patent is a valuable incentive for entities to distribute humanitarian technologies through licensing or other means. Our hope is that this new program will incentivize innovators to develop technologies that will benefit those in need."

AIPLA said in its November 19, 2010, comment that the current proposal "is unlikely to achieve the desired results, and may create the undesirable impression that reexamination is a necessity because issued patents are inherently unreliable or defective." AIPLA recommended instead that adopting "accelerated, careful examination of initial patent applications (and possible

reissue applications) would better advance the expressed interests of the proposal." *See The National Law Journal*, November 22, 2010.

NEW BIOBUSINESS VENTURES

GE Unit Invests in BioFuels

GE Energy Financial Services, a unit of General Electric, recently announced that it has joined North Bridge Venture Partners to invest $8 million in CoolPlanetBioFuels, a Camarillo, California-based startup company that is developing a biofuel production process to convert low-grade biomass, including woodchips, crop residues and non-food fuel crops, into high-grade fuel. "CoolPlanet's low-capital process yields high-value products including gasoline," said GE Energy Financial Service's Kevin Skillern in a joint press release.

North Bridge's Basil Horangic was quoted as saying that the fuel market was one of the world's largest at approximately "$4 trillion per year. Today, biofuels are only a tiny portion of that market, but are poised for rapid growth based on concerns about global warming and importing oil. CoolPlanet's technology could be a major driver in expanding the use of low carbon footprint and locally sourced fuels." *See GE/North Bridge Press Release*, November 17, 2010.

Startup Formed to Commercialize Nanotech Cancer Treatment

According to a news source, two University of Missouri researchers have partnered with an India-based pharmaceutical company to launch Shasun Nanoparticle Biochem Inc., which will bring a prostate cancer treatment using gold nanoparticles to market. Nanotechnology researcher Kattesh Katti, who has been studying the technology for more than five years, was quoted as saying, "When we injected the nanoparticles" into the tumors of lab mice, "they did not leak out, [and] we noticed about an 85 percent reduction in tumor volume." They expect to seek Food and Drug Administration approval for the therapy in the next 12 to 18 months.

The startup, based at the University of Missouri, will reportedly advance to testing in humans with the help of a $1.5 million initial investment by Shasun Parmaceuticals Ltd., which has the capacity to manufacture the drug with plants in India and the United Kingdom. *See The Columbia Daily Tribune*, December 2, 2010.

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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BIOTECH LEGAL BULLETIN

ISSUE 4 | DECEMBER 16, 2010

INVESTOR NEWS

Israeli Biotechnology Startups Seek Partnerships in Ohio

Israeli biotechnology companies are reportedly heading to Ohio because of state incentives and a venture capital fund focused on investing in Israel. Rick Shottenstein, Ohio Department of Development's Tel Aviv representative, told a news source that he frequently meets with representatives of Israeli companies interested in linking with Ohio medical experts, clinics and investors. "It's a total avalanche" he was quoted as saying.

Michael Goldberg, founder and managing partner of a Cleveland-based investment fund, reportedly said that in the past eight years some 14 Israeli technology startups have raised money from Ohio-based backers, with at least six opening offices in the state. Approximately five Israeli biotech companies plan to move to Ohio, he said, with dozens more cooperating with clinical research associated with Ohio-based groups. "While many Israelis still look to Boston or Silicon Valley for support, Ohio has done more than other states to attract Israeli startups," Goldberg said. *See Bloomberg,* November 17, 2010.

New Biotech Initiative in San Francisco

San Francisco has reportedly started a new initiative to expand biotech and life-sciences startups in areas that include Mission Bay, Pier 70 and the former Hunters Point Naval Shipyard. BioSF is described as a "unique public, academic and private partnership that brings together the city, California Institute for Quantitative Biosciences and the San Francisco Center for Economic Development to hire a joint biotech industry manager," who will develop and promote the city's biotech industry. According to Mayor Gavin Newsom (D), the program is "another major step in the city's ability to remain a world leader in biotechnology."

Newsom announced the initiative in conjunction with the opening of Nektar Therapeutics' new 102,000-square-foot Mission Bay headquarters. The life sciences company, which is apparently the 73rd such enterprise now in the city, will reportedly bring 150 biotech jobs to San Francisco. *See San Francisco Chronicle, Mayor Gavin Newsom Press Release,* November 18, 2010.

Barbados Launches Biotech Initiative Designed to Shorten R&D Process

The Barbados government has recently launched two initiatives to attract biotech companies to the island nation. According to Invest Barbados, the country's economic development agency, the initiatives create a "state-of-the-art laboratory for world-class research and development initiatives and the establishment of a regulatory authority to oversee biotech R&D to international standards."

David Estwick, the nation's minister of agriculture, food, fisheries, industry, and small business development, was quoted as saying that the initiatives will enable biotech companies to shorten the R&D approval process by more than a year. "Similarly, by providing government-owned land for the creation of a state-of-the-art biotech R&D center in a U.S. $20-million joint venture arrangement with the private sector, we will provide rental space for entrepreneurs seeking to develop new biotech products to pursue their visions," he said. "Moreover, their efforts to grow and prosper in world markets will be protected by the strong intellectual property legislation Barbados already has in place, as well as our tax-efficient international business legislation." *See Invest Barbados Press Release,* December 1, 2010.

Helix Therapeutics Secures $2.5 Million for Stem Cell Gene Correction Therapy

Helix Therapeutics, a New Haven, Connecticut-based biopharmaceutical company, has reportedly secured $2.5 million in new funding "to further its proprietary targeted gene modification technology platform, which allows correction of certain genetic mutations in blood stem cells of patients with rare genetic diseases." The funding will come from venture firm Canaan Partners and Connecticut Innovations, a quasi-public entity.

Helix officials have said the funding will help the company pursue therapies for genetic disorders, including sickle cell anemia, B-Thalassemia and lysosmal storage disorders. The company's technology, developed at the Yale University School of Medicine, "uses patented oligonucleotides that bind to the human genome resulting in permanent, target gene modification," according to a news source. *See PR Newswire,* November 23, 2010.

BUSINESS CLIMATE

Eleanor Herriman, "The U.S. Biosimilars Market—More 'Bio-me-too' Than 'Biogeneric?'" *BNA Life Sciences Law & Industry Report*, December 3, 2010

This article contends that the market for biosimilars is unlikely to be "robust" because "[w]hen the complex and unpredictable biochemistry of biologics confronts the risk-averse nature of our regulatory body and health care industry, as well as the economics of our biopharmaceutical industry, markets evolve slowly." The author contrasts the development of biosimilars, involving such challenges as the variability and "messiness" of proteins, to the development of generics, "small molecule therapeutics [that] can be reproduced in 'identical ways," and are "inherently safe to clinicians and patients." The "not really very similar" problem of biosimilars then, "affects regulatory, branding, marketing, and economic issues, and ultimately will determine to what extent the market behaves like a generics one at all," according to the author.

She notes the time-consuming nature and high cost of biosimilar clinical trial development in the European Union, where a biosimilars approval pathway has been in place for several years. Because U.S. oversight agencies may follow the European model, where clinical trial requirements are made on a case-by-case basis, costs are predicted to run eight to 100 times more than the costs involved in developing generics. The article concludes by observing that biosimilars without interchangeability designations are not likely to be adopted by physicians, "especially if savings are not meaningful due to minimal price discounts." The author suggests that any responsible market predictions will depend on how the Food and Drug Administration decides to regulate biosimilars.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

USPTO Seeks Comments on Rules for *Ex Parte* Patent Appeals

The U.S. Patent and Trademark Office (USPTO) has issued a notice of proposed rulemaking that seeks public comments on proposed new revisions to current procedures governing practice before the Board of Patent Appeals and Interferences. The proposed changes are intended to "avoid undue burden on appellants or examiners to provide information from the record to the Board, to eliminate any gap in time from the end of briefing to the commencement of the Board's jurisdiction, to clarify and simplify petitions practice in appeals, and to reduce confusion as to which claims are on appeal." Written comments must be submitted by January 14, 2011. *See Federal Register*, November 15, 2010.

EPA Approves Biofuel Additive

Gevo Inc., a Colorado-based renewable chemicals and advanced biofuels company, recently announced that the Environmental Protection Agency (EPA) has cleared its isobutanol for use as a fuel additive. EPA's approval reportedly makes Gevo the first company to have isobutanol listed in the EPA's Fuel Registration Directory. "Gevo's isobutanol can be used directly as a specialty chemical, as a gasoline and jet fuel blendstock, and through conversion into plastics, fibers, rubber and other polymers," according to the company.

Gevo has also announced that it will begin the retrofit of its first 22 million gallons per year (MGPY) ethanol facility in Luverne, Minnesota, to produce 18 MGPY of isobutanol. "The company plans to expand its isobutanol production via the retrofit of additional ethanol facilities over the next two years. In the future, Gevo intends to produce cellulosic isobutanol once biomass conversion technology is commercially available." *See Gevo Press Release*, November 11, 2010.

USDA Proposes Adding 14 Product Categories to Its BioPreferred List

The U.S. Department of Agriculture (USDA) has issued a **proposed rule** that would add 14 biobased product categories to its list of preferred items for federal procurement under the agency's BioPreferred Program. The proposal represents the seventh round of items to be designed as BioPreferred since 2006. Public comments are requested by January 24, 2011.

The proposal adds "animal repellents; bath products; bioremediation materials; compost activators and accelerators; concrete and asphalt cleaners; cuts, burns, and abrasions ointments; dishwashing products; erosion control materials; floor cleaners and protectors; hair care products; interior paints and coatings; oven and grill cleaners; slide away lubricants; and thermal shipping containers." USDA has proposed minimum biobased contents for each item. Manufacturers can claim BioPreferred status for their products once they are deemed eligible for the program. *See Federal Register*, November 23, 2010.

LITIGATION

Appeals Court Considers Federal Funding of Stem Cell Research

A D.C. Circuit Court of Appeals panel recently heard argument on whether new National Institutes of Health (NIH) guidelines pertaining to federal funding of embryonic stem-cell research violate a law that places certain restrictions on such research. *Sherley v. Sebelius*, No. 10-5287 (D.C. Cir., argued December 6, 2010). The challenge was brought by two scientists who work with adult stem cells and contend that that the NIH guidelines have put them at a competitive disadvantage in terms of securing federal funding. A district court ordered the U.S. Department of Health and Human Services and NIH to stop funding embryonic stem-cell research, and the appeals court stayed the order pending its review of the decision.

According to a news source, one of the scientists, James Sherley, works for a biomedical research institute that joined an *amicus* filing directly opposing its employee in the suit. The Boston Biomedical Research Institute has apparently informed the court that it was restricted by the lower court's injunction from expanding its research to include the use of human embryonic stem cells and has been forced to reject a university and foundation offer to provide the institute with human embryonic stem cells with mutations conferring muscular dystrophy for its research.

A government lawyer reportedly argued that the government is not paying for research that endangers or destroys human embryos, seeking to distinguish research that creates stem-cells and in the process destroys embryos from research using the differentiated cells developed from the stem-cell

lines. She apparently indicated that the stem cell lines used in federally funded research may have been created years earlier, and that Congress did not intend to ban funding for any research using embryonic stem cells. The NIH guidelines allow research on cells derived from embryos that would otherwise be disposed of after *in vitro* fertilization procedures. *See Associated Press*, November 22, 2010; *The National Law Journal* and *Bloomberg Businessweek*, December 6, 2010.

Federal Circuit Upholds Sanctions Against Plaintiff and Counsel

The Federal Circuit Court of Appeals has denied a motion seeking to stay an award of $631,000 in sanctions and fees against a company and its counsel for bringing a baseless infringement claim involving an information processing methodology. *Eon-Net LP v. Flagstar Bancorp, Inc.*, No. 2009-1308 (Fed. Cir., decided November 16, 2010) (nonprecedential). In an earlier ruling on sanctions against counsel, the court noted that "indicia of extortion" were present in the case, with the plaintiff offering "a nuisance settlement at the outset to avoid a hard look at the merits of its infringement claim." According to the court, neither the plaintiff nor its counsel showed irreparable harm if required to pay the sanctions. Their declarations in support of their claim of counsel's alleged poverty were unsupported by documentary evidence.

NEWS BYTES

The European Medicines Agency (EMA) adopts two draft guidelines as part of the regulatory approval process for certain biosimilar medicinal products. Public comments on both are requested by May 31, 2011. The guidelines address "**similar biological medicinal products containing monoclonal antibodies**" and "**immunogenicity assessment of monoclonal antibodies intended for in vivo clinical use**."

The Food and Drug Administration issues a **notice** asking patient and consumer advocacy groups, health care professionals and academic experts to tell the agency if they intend to participate in "consultation meetings relating to the development of a user fee program for biosimilar and interchangeable biological product applications submitted under the Public Health Service Act." Notification of intention to participate is requested by January 10, 2011.

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BIOTECH LEGAL BULLETIN

ISSUE 4 | DECEMBER 16, 2010

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner Michelle Fujimoto will join a distinguished panel of speakers addressing biotech industry developments at the Midyear Meeting of the International Association of Defense Counsel. Scheduled for February 19-24, 2011, in Pebble Beach, California, this conference features a number of presentations, including the Drug, Device and Biotechnology Committee's program, "The Immediate Future: What Practitioners Need to Know Regarding Developments in the Industry and Their Impact on the Practice of Law." Fujimoto will join three other speakers during this program to discuss issues likely to affect the industry over the next five years, including "the increased use of nanotechnology, biopharmaceuticals, and biosimilars," how these developments may affect the business side of the industry and their likely effects on litigation practices.

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BIOTECH LEGAL BULLETIN

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