Shook, Hardy & Bacon L.L.P.

ISSUE 11 | APRIL 7, 2011

BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

FTC Report Recommends Ways to Balance Patent System with Competition

The Federal Trade Commission (FTC) has issued a report titled "The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition." Based on stakeholder hearings, a workshop and public comments that explored how well the U.S. patent system and competition policy work together, the report provides specific recommendations for ensuring that innovations are not stifled and damages for infringement are adequate.

Many of the recommendations arose from concerns expressed by the information technology industry. They call for improvements to patent claims so that they better fulfill their notice function ("patent claims must delineate the scope of patent rights with sufficient clarity that a person skilled in the relevant art can reliably determined whether planned activities would infringe"); definitions for key claim terms, as well as a U.S. Patent & Trademark Office-sponsored "workshop to explore ways of fostering greater uniformity in the methodology or language used for describing and claiming software inventions"; and improvements to clearance searches. The report also contains a number of recommendations for more accurately assessing infringement damages in an effort to "derive an economically grounded approach to calculating patent damages." According to FTC, another improvement to the system would be for courts to exercise their gatekeeper authority and exclude unreliable expert testimony on damages.

INVESTOR NEWS

Synageva Announces $25 Million for Rare Disease Product Development

Synageva BioPharma Corp. has announced an additional $25 million in private equity financing to support therapeutic product development. According to the Massachusetts-based biopharmaceutical company, the addition brings the company's funding to $70 million and will further support its mission of providing orphan therapies to patients with rare conditions and unmet medical needs.

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SHB offers expert, efficient and innovative representation to life sciences clients facing complex biotech litigation and intellectual property and regulatory protocols. We know that the successful resolution of biotech-related matters requires a comprehensive strategy developed in partnership with our clients.

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The new financing will advance clinical studies for SBC-102, an enzyme replacement therapy for Lysosomal Acid Lipase, a rare disease that can evidently cause liver failure and death. "The company's ability to raise capital during these challenging economic times is a testament to the strength of our corporate vision and execution, the team's rare disease expertise, the product pipeline, and our ability to make these products on a commercial scale," said Sanj Patel, the company's president and CEO. *See Synageva Press Release*, March 21, 2011.

Ohio Sees Growth in Biosciences Sector

Bioscience jobs in Ohio have reportedly grown nearly 20 percent in the past decade and represent 62,500 workers, according to a **report** from BioOhio, a biomedical advocacy group.

Citing statistics from 2000 to 2009, the report found that bioscience companies accounted for a $4.3-billion payroll, with jobs in medical and testing laboratories, pharmaceuticals and therapeutics, and research and development representing the fasting-growing fields within the biosciences sector.

"Ohio's bioscience ecosystem is healthier than ever and resources are constantly being added or enhanced," BioOhio's president was quoted as saying.

In related news, Akron, Ohio, Mayor Don Plusquellic (D) announced **plans** to form a fund aimed at attracting early-stage biomedical companies to the city's newly designated downtown biomedical corroidor and then "help them grow into their own space." In a March 22, 2011, state of the city address, the mayor said that the Akron Development Corporation Seed Fund has received $1 million from its first sponsor, Medical Mutual of Ohio, and that the power company FirstEnergy has committed to becoming an investor.

Bob Bowman, Akron's deputy mayor of economic development, told a news source that the city plans to target approximately $15 million for the fund and make its first investment by summer 2011. Most investment amounts would range from $100,000 to $250,000 from corporate donations and other sources, he said. *See MedCity News,* March 23 and March 31, 2011.

BUSINESS CLIMATE

Biotech Companies Struggling in Public Markets

While five venture-capital backed biotech companies have reportedly gone public in 2011, each has been forced to lower its offering price even before the initial public offering took place due to weakened demand. These companies have reportedly looked to public markets to secure needed funds and keep their clinical trials going, but have been unable to attract the capital they need for late-stage venture endeavors. This could, according to some analysts, give

corporations an edge in partnership and merger negotiations with biotech startups. *VentureWire's* Brian Gormley writes, "Venture investors do not count on IPOs to cash out of biotech holdings, as often done with technology companies, but they do see the public markets as a vital option for companies that need a big cash infusion. Weak demand for these offerings is restricting access to capital, depressing valuations of late-stage venture rounds. . . . For various reasons—including firms' own inability to raise funds—biotech investment is already slipping, with less money going into the field each of the last three years." *See The Wall Street Journal* and *VentureWire*, April 4, 2011.

Market Study Highlights Key Algae Biofuel, Biochemical Success Traits

Emerging Markets Online recently released an **algae study** that "highlights why some algae companies will be winners and some will be losers bringing their product from pilot to commercial scale from 2011-2020."

Authored by Will Thurmond, *Algae 2000: Vol. 2: Global Biofuels, Drop-In Fuels, Biochems, Markets and Forecasts* contains information based on more than 200 interviews with CEOs and key researchers from algae-related companies, universities, research labs, public-private partnerships and collaboratives, and 30 algae industry site visits.

Concluding that fewer than 12 current algae production companies, R&D ventures and public-private partnerships will "graduate into pre-commercial, deployment-stage algae ventures using pond, photo-bioreactor and fermentation based production systems," the study forecasts that surviving companies "will expand globally and multiply leading to hundreds of projects, markets, products, and co-branded ventures."

According to Thurmond, key strategies that "algae winners" use to help attract capital and scale are (i) diversifying their fuels "beyond just algae for biodiesel"; (ii) targeting diversified markets on "high-value products including omega 3s, health products, cosmetic, pharmaceutical, and specialty chemical uses, and some mid-value markets like livestock and fish meal, renewable chemicals"; and (iii) bringing R&D labs, universities and public-private partnerships together in "collaborative clusters" to focus on key technology challenges and "market demand-based opportunities." *See 4R Communications Press Release,* February 22, 2011; *Renewable Energy World*, March 29, 2011.

Russia Sets Global Biotech Market Goals

According to a news source, Russia intends to increase its participation in the global biotechnology market to a 5 percent share by 2020. Russian companies now apparently hold a 0.2 percent market share. Prime Minister Vladimir Putin reportedly expressed concerns to government ministers and entrepreneurs during an April 1, 2011, meeting that the nation was lagging behind China, India and Brazil. He was quoted as saying, "Our job is to change the situation, to

create conditions for formation of [a] powerful biotech sector in Russia." While the government has injected significant funds into nanotechnology in recent years, Russia's Deputy Economy Minister Andrei Klepach did not indicate whether that will be matched in the biotech sector. Still, three of the 25 "technology platforms" the government recently approved to provide a framework and coordination for research and funding involve biotechnology. *See Reuters*, April 1, 2011.

Biosimilars Market Expected to Increase by Billions over Next Four Years

Market analysts have apparently forecast huge growth in the market for biosimilars due to the upcoming loss of patent exclusivity for a number of branded drugs. Datamonitor has reportedly indicated that it expects the worldwide market for copies of biotech prescription drugs to grow from $243 million in 2010 to approximately $3.7 billion by 2015. The projections are based on the 30 branded biologics with sales exceeding $50 billion that will lose their patent protection between 2011 and 2015. Generic drugmakers have been moving into the biosimilars market; they have been joined by several global branded pharmaceutical companies. *See Reuters*, March 28, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

House Lawmakers Introduce Version of Patent Reform Law

U.S. Representatives Lamar Smith (R-Texas), Bob Goodlatte (R-Va.) and Darrell Issa (R-Calif.) have introduced their **version** of the America Invents Act (AIA), which was recently approved by the U.S. Senate. According to a leading patent law blog, the House bill parallels the Senate version in many ways, including mandates that switch to a first-to-file system, establish a modified *inter partes* reexamination and post grant opposition system, and provide the U.S. Patent & Trademark Office with fee-setting authority.

Key differences between the new proposal and the Senate version apparently include (i) "details of the post grant opposition provision"; (ii) "prior user rights"; (iii) "special business method proceedings, venue restrictions, interlocutory appeals, and attorney fee shifting"; (iv) "automatic stay of litigation for *inter partes* reviews"; (v) "elimination of tax strategy patents"; and (vi) "codification of *Knorr Bremse* (failure to present advice of counsel cannot be used as evidence of willful infringement." *See PatentlyO.com,* March 31, 2011.

Minnesota Legislators Approve Bills Limiting Stem Cell Research; Governor Vows Veto

The Minnesota Legislature has reportedly approved bills that would prohibit the use of state or federal funds to support certain types of stem cell research. The Senate bill (**S.F. No. 924**) was introduced as an amendment to the omnibus appropriations bill; it would prohibit funding for human cloning.

The Senate's amendment states that cloning "means generating a genetically identical copy of an organism at any stage of development by combining an enucleated egg and the nucleus of a somatic cell to make an embryo," a technique that can evidently be used to create stem cells. The proposal was reportedly the subject of heated debate, with some arguing that it misled the public on embryonic stem cell research by failing to distinguish between "reproductive cloning"—the first step in the cloning of a human—and "therapeutic cloning," which involves the creation of a small number of cells for use in the treatment of disease.

After University of Minnesota researchers expressed concern about the impact the Senate's legislation might have on therapeutic cloning, a corrective amendment was added to a higher education funding bill in the House, (H.F. 1101), which was also passed. This amendment would exempt funding for medical research and further provides that "nothing in this section shall affect the scientific field of stem cell research, unless explicitly prohibited."

Minnesota Governor Mark Dayton (D-Farmer-Labor) sent a letter to Senate Majority Leader Amy Koch and House Speaker Kurt Zellers promising to veto any funding bills with "extraneous policy items" like this. "If I reject those items, and therefore the bills containing them have to be returned for separate passage, those delays will be the Legislature's responsibility, not mine," Dayton wrote. *See MNDaily.com,* March 29, 2011.

LITIGATION

Court Dismisses French Company from Suit Seeking Correction of Patent Inventorship

A federal court in the District of Columbia has dismissed patent-related litigation against a French drug company for lack of personal jurisdiction. *Adm'rs of the Tulane Educ. Fund v. Ipsen Pharma, S.A.S.*, No. 09-2428 (U.S. Dist. Ct., D.D.C., decided March 14, 2011). Tulane University and one of its research professors filed an action against Ipsen Pharma, S.A.S. (Ipsen Pharma) and Ipsen, S.A. (Ipsen) for "correction of inventorship" of several U.S. patents and for damages under Massachusetts state law for unfair business practices, unjust enrichment and constructive trust. The patents at issue cover the results of research into biologically active fragments and analogs of various peptides that are anticipated for use in the treatment of diabetes and obesity.

Ipsen is a French company that holds more than a 95 percent of the share capital and voting rights of its subsidiary Ipsen Pharma, which holds Ipsen's intellectual property rights. Ipsen and/or Ipsen Pharma have developed and marketed a drug for the treatment of Type 2 diabetes. Ipsen filed a motion to dismiss the claims against it, contending that the court lacked personal jurisdiction over the company.

The court agreed, finding that Ipsen could not be sued as a foreign patentee under section 293 of the U.S. Patent Act. According to the court, Ipsen Pharma is the assignee of record at the U.S. Patent & Trademark Office for the patents at issue. Because the plaintiffs failed to allege that Ipsen itself was the owner or successor of any of the patents, it could not be sued as the patentee. The court also rejected the plaintiffs' argument that Ipsen could qualify as a patentee under section 293 as a party "who obtains the benefit of a patent." According to the court, this would constitute a novel statutory interpretation. The court further refused to pierce the corporate veil between Ipsen and its subsidiaries, because this issue had earlier been adjudicated and determined by a federal district court in Louisiana and because nothing in the record indicated that Ipsen and Ipsen Pharma were alter egos.

Adequacy of Generic Drug Warnings on U.S. Supreme Court Agenda

The U.S. Supreme Court is considering whether a generic drug maker can be held liable under state law for failing to include on its drug label safety information not yet used by name brand manufacturers or required by the Food and Drug Administration (FDA). *PLIVA, Inc. v. Mensing*, No. 09-993 (U.S., oral argument, March 30, 2011). The product at issue was the generic bioequivalent of a drug prescribed to treat the plaintiff's diabetic gastroparesis. She took the generic drug for four years and then allegedly developed tardive dyskinesia. Generic drug makers generally label their products with the warnings that FDA approves for the name brand versions, and when the plaintiff was taking metoclopramide, no manufacturer had taken steps to change the label warnings despite mounting evidence that long-term use carries a purported tardive dyskinesia risk.

The Eighth Circuit Court of Appeals reversed a lower court's grant of the generic drug makers' motion for summary judgment, finding that the plaintiff had stated a viable claim that was not preempted by federal law. According to the court, the regulatory framework "does not permit generic manufacturers passively to accept the inadequacy of their drug's label as they market and profit from it." The Eighth Circuit rejected the defendants' efforts to establish that it would be impossible for them to comply with both federal law and the state laws the plaintiff sought to enforce. The defendants argued that they are prohibited from implementing a unilateral label change without prior FDA approval, but the court observed that they "could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved."

Numerous *amicus* briefs were filed, nearly all of them on behalf of the plaintiff, who is the respondent before the U.S. Supreme Court. Among those supporting her are 42 states and the District of Columbia; various medical societies, including the American Medical Association; the U.S. government; Representative Henry Waxman (D-Calif.); and a number of legal scholars. A decision could be handed down before the Court concludes its term in June 2011.

Farmers and Seed Companies Ask Court to Declare Monsanto GE Seed Patents Invalid

A coalition of more than 50 trade organizations, seed businesses, farms, and farmers has filed a lawsuit in a federal court in New York, to stop Monsanto Co. from enforcing its genetically engineered (GE) seed patents against farmers whose fields become contaminated with the GE seeds. ***Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, No. 11-2163 (U.S. Dist. Ct., S.D.N.Y., filed March 29, 2011)**. Among other matters, the plaintiffs claim that the seed patents are invalid, because "only technology with a beneficial societal use may be patented," they violate "the prohibition against double patenting, each is anticipated or rendered obvious by prior art, and each fails to satisfy the requirements of written description, enablement and best mode."

The plaintiffs also allege that the patents are not infringed by farmers whose fields become contaminated with GE seeds, because the farmers do not intend to use them, "and Monsanto's patent rights in transgenic seed exhaust upon the authorized distribution by Monsanto to its customers." They further claim the company has "committed misuse," "is equitably stopped from enforcing" the patents and "commits trespass when its transgenic seed contaminates another."

At issue are some 23 patents, which, the plaintiffs contend, are "zealously" enforced by the company. According to the complaint, "Published reports and Monsanto's own statements suggest that roughly 500 farmers are investigated for patent infringement each year. Between 1997 and April 2010, Monsanto filed 144 lawsuits against farmers in at least 27 different states for alleged infringement of its transgenic seed patents and/or breach of its license to those patents." The plaintiffs also allege that "Monsanto has made accusations of patent infringement against those who never wished to possess its transgenic seed."

The complaint includes four claims for relief—declaratory judgments of patent invalidity, non-infringement, unenforceability and no entitlement to any remedy. The plaintiffs seek an injunction to stop the company "from taking any action to enforce any patent in suit" and an order for costs and attorney's fees.

Monsanto reportedly characterized the lawsuit as invalid and a "publicity stunt." According to the company, it has never sued farmers for the inadvertent presence of biotechnology traits in their fields. In a statement, the company said, "These efforts seek to reduce private and public investment in the development of new higher-yielding seed technologies. While we respect the views of organic farmers as it relates to the products they choose to grow, we don't believe that American agriculture faces an all-or-nothing approach."

The Public Patent Foundation, which filed the lawsuit on behalf of the coalition, disagreed that GE seed can coexist with organic seed. The foundation's executive director said, "[H]istory tells us that's not possible, and it's actually in Monsanto's financial interest to eliminate organic seed so that they can have a total monopoly over our food supply." *See Reuters* and *Public Patent Foundation Press Release*, March 29, 2011.

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NEWS BYTES

The U.S. Patent & Trademark Office implements prioritized examination of patent applications. Track One, which launches May 4, 2011, requires a $4,000 filing fee and is limited to 10,000 applications; USPTO promises an expedited 12-month processing time.

The U.S. Patent & Trademark Office adopts an automated petition process for eight patent-related petition types to speed up processing for matters that take up one-third of the Petition Office's work.

The National Advisory Council for Biomedical Imaging and Bioengineering announces a May 20, 2011, meeting in Bethesda, Maryland, to consider a report from the National Institutes of Health director and discuss a strategic plan.

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Intellectual Property Partner Peter Strand will lead a session on communicating with jurors at DRI's Business Litigation and Intellectual Property Seminar slated for April 14-15, 2011, in Chicago, Illinois. Titled "A Thousand Words More or Less: Effectively Using Visuals at Trial," the presentation will address "the 'whys' and 'hows' of teaching and persuading jurors using the entire panoply of visual media."

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