Shook, Hardy & Bacon L.L.P.

ISSUE 2 | NOVEMBER 4, 2010

BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

U.S. Supreme Court to Decide Whether Stanford Owns Patents for Invention Funded with Federal Dollars

The U.S. Supreme Court has granted the appeal of a Federal Circuit decision that rejected on standing grounds a university's claim to patents that arose out of an NIH-financed research project involving technology for detecting HIV levels in a patient's blood. *Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, No. 09-1159 (U.S., *cert*. granted November 1, 2010). The issue raised on appeal is stated as: "Whether a federal contractor university's statutory right under the Bayh-Dole Act, 35 U.S.C. §§ 200-212, in inventions arising from federally funded research can be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor's rights to a third party."

The case involves three patents obtained between 1999 and 2006, all of which were purportedly assigned to Stanford. One of the inventors also assigned the rights to his inventions to a company that he regularly visited to learn the polymerase chain reaction (PCR) technique used in the patented HIV-detection methods. The company and Stanford entered several agreements relating to materials used in the research and licenses to the technology developed by Stanford's researchers. Later, Stanford and the company's successor were unable to reach a licensing agreement involving the patents, and Stanford sued the successor for infringement when the company started selling kits for PCR detection of HIV RNA to assess the efficacy of antiretroviral therapy.

A federal district court ruled that the successor's assertion of ownership rights was barred by the statute of limitations and that it did not have a license to the technology because it failed to obtain the patent holder's—Stanford's—consent. Still, the court determined that the three patents were invalid for obviousness.

The Federal Circuit determined that the lower court erred by failing to consider the successor's ownership claims because it had raised the issue of Stanford's standing and this matter was not foreclosed by the statute of limitations. Looking at the language of the inventor's various assignments of rights, the court concluded that he made "a mere promise to assign rights in the future" to the university, but effected an immediate transfer of rights which he still held to the company when assigning his rights to it. The Federal Circuit ruled that the successor's ownership interest in the patents defeated Stanford's standing to sue for infringement.

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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 Federal Circuit rejected the university's interpretation of the Bayh-Dole Act, finding no authority or persuasive reason "why its election of title under Bayh-Dole had the power to void any prior, otherwise valid assignments of patent rights." Apparently, Stanford notified the government about its intention to elect to retain title to the patents more than six years after the inventor assigned his rights to the company. Stanford argues that the Bayh-Dole Act limits an inventor to a contingent right that vests only if the university does not elect to retain title within a reasonable period of time. Because the university made that election, it argues that the inventor's contingent right was extinguished.

NEW BIOBUSINESS VENTURES

Samuel Waksal Starts Biopharmaceutical Company

Samuel Waksal, the former ImClone Systems chief executive released from federal prison less than two years ago after serving a sentence for crimes that included alleged insider stock trading, has reportedly started a new "fully integrated biopharmaceutical company." Kadmon Pharmaceuticals will focus on cancer, infections and autoimmune diseases, conduct its own research and acquire products already on the market or in clinical trials.

"You'll see a company that next year will be doing significant revenues in a growth area, with earnings, probably five Phase 3 programs and a couple of Phase 2 products," Waksal told a news source. The company's first reported major deal involved acquiring the privately held Three Rivers Pharmaceuticals, a Pennsylvania company that primarily produces drugs to treat hepatitis C. "The hep C market is going to undergo a real sea change next year," Waksal said.

Kadmon has also apparently bought a small company started by Princeton professors who developed a way to measure cell metabolism which could help lead to treatments for cancer and infectious diseases. *See The New York Times*, October 31, 2010.

INVESTOR NEWS

Illinois Leads Midwest Region in Venture Capital

According to data compiled by BioEnterprise, health care startups in the Midwest attracted $572 million in venture capital in the first three quarters of 2010, with companies in Illinois and Ohio leading the way. Companies in those states attracted $148 million and $89 million respectively. Biopharmaceutical companies in the region received $345 million in investments, while medical device companies received $190 million. Health care investors were somewhat surprised by the apparent credit market thaw and at least one indi-

cated that locating proven senior management talent remains a challenge. *See BioEnterprise Press Release* and *MedCity News*, October 28, 2010.

New Biotech Labs and Research Institutes Proliferating

With hopes of a better economic climate on the horizon, government, academia and the private sector throughout the United States are hoping to lure business with the development of state-of-the art biotech research facilities. According to recent reports, University of Louisville officials in Kentucky have dedicated a $44 million biosafety lab that will focus on developing vaccines and treatment for infectious diseases. Scheduled to begin operations in late 2010, the lab is among 14 in the region funded by the National Institute of Allergy and Infectious Diseases since 2001. *See courier-journal.com*, October 18, 2010.

The Vaccine and Gene Therapy Institute of Florida has begun building a 100,000-square-foot biomedical research facility in Port St. Lucie that will more than double that city's biotech industry. Slated to open in 2012, the campus will eventually have 200 employees working on infectious diseases such as AIDS and Dengue fever. The governor's office has reportedly estimated that the institute and related startup enterprises will, in their first 20 years, either directly or indirectly create nearly 1,500 jobs and $2 billion in payroll. *See The Palm Beach Post*, October 20, 2010.

Two commercial laboratory complexes are under development in New York City, as part of an initiative to develop a bioscience industry there. The Alexandria Center for Life Science-New York City is a $200-million tower complex, most of which is expected to be occupied by the end of 2010. Developer Alexandria Real Estate Equities is planning to add two additional towers as part of the complex, at a total cost of $600 million to $700 million. The New York City Economic Development Corporation and the SUNY Downstate Medical Center are reportedly developing BioBAT in the Brooklyn Army Terminal. Phase one, which will begin in early 2011, will create 60,000 square feet of lab space on the south side of the 1.8-million-square-foot building. Forty-thousand square feet on the north side of the building has been occupied by the International AIDS Vaccine Initiative for nearly two years. Its executive director is looking forward to welcoming other biotech companies or startups to the area. Both New York City development projects have reportedly received significant government subsidies and face stiff competition from suburban facilities that offer turn-key space. *See The New York Times*, October 19, 2010.

Campaign Seeks to Reinforce Hudson Valley as a Biotech Industry Hub

Senator Kirsten Gillibrand (D-N.Y.) and business leaders have reportedly unveiled a "NY BioHud Valley" campaign that highlights the state's Hudson Valley as a "burgeoning epicenter of the biotech industry." According to Gillibrand, more than 60 biotech companies that deal with innovations including

clean energy and new pharmaceuticals are located in the Hudson Valley's seven counties.

"NY BioHud Valley is the future of our economy here in the Lower Hudson Valley," Gillibrand was quoted as saying. "We are home to a well-educated workforce, world-class research institutions, medical centers, laboratories, and academic research organizations."

The campaign, a public-private partnership, will target biotech companies, brokers, property owners, and real estate developers for continued biotech expansion. "Hudson Valley is producing a critical mass of industry, research and commercial R&D in the area of biotechnology," Nathan Tinker of the New York Biotechnology Association reportedly said. "This is a major key to cluster development and creating the sorts of relationships between companies, work forces and end-users of the product." *See Business Wire*, October 26, 2010; *Kirsten Gillibrand Press Release*, October 27, 2010.

BUSINESS CLIMATE

Level of Twitter® Calmness Claimed to Be Stock Market Predictor

According to a **study** from the Indiana University's Center for Complex Networks and Systems Research, a mood analysis of millions of daily Twitter® posts is correlated to or "even predictive of DIJA [Dow Jones Industrial Average] values." Johan Bollen, Huina Mao & Xiao-Jun Zeng, "Twitter Mood Predicts the Stock Market," October 14, 2010. The researchers apparently applied OpinionFinder, which measures positive and negative mood, and the Google-Profile of Mood States, which measures six mood dimensions—calm, alert, sure, vital, kind, and happy—to nearly 10 million tweets posted by some 2.7 million users during a 10-month period in 2008. They purportedly found that "calm" data can match shifts in DIJA values that occur three to four days later with an 87.6 percent accuracy and contend that such analysis "offers an automatic, fast, free and large-scale addition to [the public mood market model] toolkit."

And while market prognosticators might find Twitter® analyses useful, Malcolm Gladwell, writing in *The New Yorker*, makes a persuasive case that social media such as Twitter® and Facebook® are incapable of bringing people together to foment rebellion. He discusses the 1960 Woolworth's lunch counter sit-ins and other civil rights protests to demonstrate that their success was due to the strong ties the participants had to each other, as well as the hierarchical organization, discipline and strategy that allowed individuals to take on a powerful and organized establishment. Gladwell suggests that social media, which are built around weak ties, "seldom lead to high-risk activism." Social networks "have real difficulty reaching consensus and setting goals. They can't think strategically; they are chronically prone to conflict and

error." While they can be good at giving people access to information, they do not "help us persevere in the face of danger." *See The New Yorker*, October 4, 2010.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Presidential Commission to Consider Bioethical Issues at Public Meeting

The U.S. Department of Health and Human Services has **announced** a November 16-17, 2010, public meeting in Atlanta, Georgia, of the Presidential Commission for the Study of Bioethical Issues. Meeting for the third time since its November 2009 inception, the commission will "continue discussing the emerging science of synthetic biology, including its potential benefits and risks, and appropriate boundaries and principles" the federal government should take "to ensure that America reaps the benefits of this developing field of science." The meeting will be Webcast at **www.bioethics.gov**.

Charged with identifying and promoting policies and practices that ensure ethically responsible conduct of scientific research, health care delivery, and technological innovation, the commission also will "examine diverse perspectives and explore possibilities for useful international collaboration on these issues" and "recommend legal, regulatory, or policy actions as appropriate." The commission welcomes public comment. *See Federal Register*, October 28, 2010.

Senators Contend Antitrust Provisions on Generic Drugs Included in Wrong Bill

Several Senate Democrats have joined their Republican colleagues in a request that Senate leaders remove the "Preserve Access to Affordable Generics Act" (S. 369) from a fiscal year 2011 appropriations bill (S. 3677). The October 21, 2010, **letter**, signed by Senators Arlen Specter (D-Pa.), Robert Casey (D-Pa.), Frank Lautenberg (D-N.J.), Tom Carper (D-Del.) and Kay Hagan (D-N.C.), contends that the inclusion of antitrust provisions "contradicts both the spirit and letter of the Senate rules."

The antitrust provisions would make it more difficult for generic drug makers to settle lawsuits challenging the patents held by brand-name companies by agreeing to payments in exchange for delaying production and sale of cheaper generic products. Under S. 369, these agreements would be presumptively anticompetitive. Apparently, the Federal Trade Commission (FTC) claims these settlements are a form of collusion that keep affordable drugs off the market and, if banned, could save consumers $3.5 billion annually. The House reportedly passed a companion version in March as part of a supplemental appropriations package.

Republican Senators have also asked for the provisions to be dropped from the appropriations bill, which will likely be considered during the post-election lame-duck session. The September letter from Senators Jeff Sessions (R-Ala.), Tom Coburn (R-Okla.), John Cornyn (R-Texas), and John Thune (R-S.D.) complained that S. 369 would give excessive authority to the FTC over these settlements. *See The Hill*, October 26, 2010.

European Commission Proposes Allowing Some GM Material in Animal Feed Imports

The European Commission has reportedly finalized draft rules that would permit up to 0.1 percent unapproved genetically modified (GM) material in animal feed imported to the European Union. The GM material must have the exporting country's approval, and EU approval must be pending. According to a news source, the proposal is intended to avoid a repeat of EU animal feed supply disruptions that occurred in 2009 when U.S. soy cargoes were blocked due to the detection of unapproved GM material traces.

EU government experts will discuss the proposal on November 15, 2010, and, if it is approved, EU ministers and lawmakers will have three months to accept or reject it. The EU's ban on unapproved GM material in food imports will not change under this proposal; any amendment to relax the food standard was vigorously opposed by several countries including Germany. Exporting nations, such as the United States, Brazil and Argentina, have argued that inconsistent rules for food and feed will be unworkable. *See Reuters*, October 26, 2010.

UK Takeover Panel Poised to Modify Rules on Hostile Takeover Bids

The U.K. Panel on Takeovers and Mergers has **announced** that it plans to amend the Takeover Code to reduce the tactical advantage that hostile offerors have under the current code, particularly when short-term investors unduly influence the outcome of hostile offers to the detriment of the offeree company and its shareholders.

The Takeover Panel, which regulates takeover bids and other merger transactions for companies with registered offices in the U.K. if their securities are traded on regulated markets, has determined, among other matters, that (i) an offer's announcement can destabilize the offeree company "and often leads to significant changes in the composition of the shareholder register"; (ii) a drawn-out bid period "can adversely affect the conduct of the offeree company's business and the offeree company board's negotiation position with an offeror"; (iii) an offeror is often able to bypass the offeree company's board and deal directly with shareholders in discussing the merits of an offer and the price at which it might be made; and (iv) while the costs to offerors of making a possible offer announcement are not significant, the offeror receives protections under the code "in restraining the offeree company from taking

any action that might frustrate the offer."

The proposed changes would shorten the period between the announcement of a possible bid and the receipt of a firm offer, require more complete financial disclosures by both companies, give employees more of an input on possible mergers, and make offer-related fees more transparent.

LITIGATION

U.S. Government Takes Position on Patentability of Isolated Genomic DNA

The U.S. Department of Justice has filed an **amicus brief** in a lawsuit pending before the Federal Circuit Court of Appeals to address the question of whether and to what extent genetic discoveries may be patented. *The Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Office (Myriad Genetics, Inc.)*, No. 2010-1406 (Fed. Cir., filed October 29, 2010).

Public reaction to the government's argument that genomic DNA isolated from the human body, without further alteration or manipulation, should not be eligible for patents was swift; some argued that the policy will "undermine U.S. global leadership and investment in the life sciences," while others applauded the decision, claiming such patents would hamper medical progress and force individuals to pay for access to information about themselves. According to the government, "The chemical structure of native human genes is a product of nature, and it is no less a product of nature when that structure is 'isolated' from its natural environment than are cotton fibers that have been separated from cotton seeds or coal that has been extracted from the earth."

The government also contends that "the district court erroneously cast doubt on the patent-eligibility of a broad range of man-made compositions of matter whose value derives from the information-encoding capacity of DNA. Such compositions—*e.g.*, cDNAs, vectors, recombinant plasmids, and chimeric proteins, as well as countless industrial products, such as vaccines and genetically modified crops, created with the aid of such molecules—are in every meaningful sense the fruits of human ingenuity and thus qualify as 'human-made inventions' eligible for patent protection under section 101." Not only is manipulated material patentable, according to the government, so are "[n]ew and useful methods of identifying, isolating, extracting, or using genes and genetic information . . . (subject to the prohibition against patenting abstract ideas), as [is] nearly any man-made transformation or manipulation of the raw materials of the genome."

Briefing in the case should be completed in mid December 2010, and the case will then be scheduled for oral argument. *See The New York Times*, November 1, 2010.

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NEWS BYTES

The Committee on Technology of the White House National Science & Technology Council invites public comment until November 30, 2010, on a draft National Nanotechnology Initiative Strategic Plan.

The Financial Accounting Standards Board delays implementation of controversial rules requiring financial statement disclosures about lawsuits and other loss contingencies.

The U.S. Patent & Trademark Office releases a joint statement with the European Patent Office agreeing to "work toward the formation of a joint patent classification system."

The U.S. Patent & Trademark Office announces expansion of a peer-to-patent pilot program with New York Law School's Center for Patent Innovations; public participation in patent examination process will now include applications in biotechnology, bioinformatics, telecommunications, and speech recognition.

The U.S. Government Accountability Office issues a report to the House Committee on Oversight and Government Reform on the Food and Drug Administration's foreign drug inspection program, stressing an urgent need for the agency to conduct more drug-safety inspections of foreign establishments.

The Food and Drug Administration publishes a request for nominations of voting members from academia and industry to serve on the agency's advisory Science Board; appropriate expertise is sought in food safety, nutrition, chemistry, pharmacology, toxicology, clinical research, epidemiology, product safety, product manufacturing sciences and quality, or other scientific specialties related to biology, bioinformatics, wireless health care devices, nanotechnology, and combination products.

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