ISSUE 20 | SEPTEMBER 1, 2011

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Italy and Spain Challenge Plans to Create Unified EU Patent Protection System

Italy and Spain filed applications before the European Court of Justice in early June 2011, seeking to annul the EU Council's Decision of 10 March 2011, which authorized cooperation among member states for the creation of unitary patent protection.

The applicants allege that the cooperation agreement was not properly approved and will adversely affect the internal EU market, "introducing a barrier to trade between Member States and discrimination between undertakings, causing distortion of competition." While a deadline for public comments on legal challenges to the decision has passed, member states may still file observations.

As we reported in Issue 10 of this *Bulletin*, the European Court of Justice found unlawful a draft agreement that would have created a European and Community Patents Court.

In late June, the EU's Competitiveness Council reached agreement under the authority of the March decision on two proposed regulations that lay out a general approach for implementing unitary patent protection. Under the current system, the European Patent Office grants patent titles, but once a European patent is granted, it becomes a national patent subject to individual member rules and must be validated in each member state. The new regulations would ensure uniform protection for inventions and set forth translation arrangements. The matter next moves to the European Parliament for negotiations.

NEW BIO BUSINESS VENTURES

Par Pharmaceutical to Acquire Anchen Pharmaceuticals for $410 Million

Par Pharmaceutical Companies, Inc. has reportedly agreed to acquire Anchen Pharmaceuticals, a company that focuses on developing and commercializing extended-release and niche generic products. The $410-million deal is

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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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expected to be completed by the end of 2011; Par will finance the transaction with cash on hand and a $350-million loan.

California-based Anchen has five commercialized products, 27 abbreviated new drug applications on file with the Food and Drug Administration and approximately 26 additional products in development. The privately held company anticipates launching eight to 10 niche generic products over the next two years. With 218 employees and more than 72,000 square feet of expandable manufacturing and warehouse facilities, the company is expected to more than double Par's product opportunities. *See Par Pharmaceutical Cos. Press Release,* August 24, 2011.

Partnership Announced to Bolster Plant Biotech Research

Reliv International Inc., Soy Labs LLC and the Missouri Plant Science Center have reportedly entered into a joint research and development partnership aimed at developing nutritional ingredients based on soy and plant biotechnology. Reliv makes nutritional supplements; Soy Labs provides soy ingredients to health-supplement formulators and manufacturers; and the Missouri Plant Science Center is a joint venture of the Missouri Technology Corp., University of Missouri System and the city of Mexico, Missouri, where Soy Labs is based.

According to a Reliv press release, the new partnership will offer the company opportunities to collaborate with other research institutions, such as the University of Illinois at Urbana-Champaign, University of Louisville, and University of California campuses in Berkeley and Davis, through its affiliation with Soy Labs. That company, which moved earlier in 2011 from California to Missouri to be the Missouri Plant Science Center's "managing tenant," has received research funding from the National Institutes of Health, U.S. Department of Defense, American Institute for Cancer Research, and Biotechnology and Biological Sciences Research Council.

"I believe this relationship between Missouri's biotech scientists, farmers, and Reliv—a successful private-sector job creator—will help strengthen our state's biotech industry and encourage further economic development," U.S. Senator Roy Blunt (R-Mo.) was quoted as saying. *See Reliv International, Inc. Press Release*, August 23, 2011.

INVESTOR NEWS

Genomatica Files Proposed IPO Targeted for Renewable Chemicals

San Diego, California-based Genomatica Inc. has reportedly filed an SEC registration statement relating to a proposed initial public offering (IPO) to raise up to $100 million to finance renewable chemicals made from microorganisms

such as *E. coli.* According to a news source, the IPO will be listed as GENO on the Nasdaq Stock Market, with proceeds targeted for, among other purposes, research and development and capital projects. The number of shares to be offered and the price range have yet to be determined.

Genomatica genetically engineers microorganisms to convert plant sugars, such as those found in corn, into chemicals that are typically made from oil and natural gas. By the end of 2012, Genomatica apparently plans to open, with Italian partner Novamont SpA, its first commercial-scale plant for making butanediol, which is used in spandex, running-shoe soles and plastics. The company also plans to convert plant sugars into butadiene, which is used to make tires, engineering polymers and latex products. *See Bloomberg,* August 24, 2011.

Aura Biosciences Reportedly Raises Almost $3 Million in New Funding Round for Nanotech Enhancement of Drug Therapies

Aura Bioscences Inc., a Cambridge, Massachusetts-based startup, has reportedly raised $2.95 million with 23 investors in its second funding round for a drug-delivery system using nanotechnology. Founded in 2009, the company has acquired approximately $4.4 million in investment backing.

Focusing initially on cancer treatments, Aura Biosciences uses its proprietary nanotech platform called Nanosmart™ to wrap therapies in a protein nanoparticle targeted to a specific tumor. According to the company, Nanosmart™ nanoparticles mimic viral structures "engineered for precise targeting, immune system evasion, and efficient cellular uptake." *See Mass High Tech,* August 26, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Bloomberg Article Parses America Invents Act

Shook, Hardy & Bacon Intellectual Property Attorneys John Garretson and Ben Tabor have co-authored an article titled "'America Invents Act': The Impact of Patent Reform" in a recent *Bloomberg Law* publication.

Raising the possibility that patent reforms currently pending before Congress could become law as early as September 2011, the authors discuss the provisions that would take effect immediately and some others that will be phased in over a 12-18 month period. Immediate changes include those that should reduce the false marking lawsuits that have clogged the courts and a provision changing the venue for litigation against the U.S. Patent and Trademark Office from the District of Columbia to the Eastern District of Virginia. Another change would "definitively abolish" state court jurisdiction for "any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights."

The authors conclude, "The 'American Invents Act' is far-reaching, comprehensive legislation that will have a profound impact on our patent system. If enacted, its full range of effects will not be apparent for several years, although some changes will take place immediately. Upon initial analysis, the Act appears likely to advance its stated purpose—to simplify and streamline the process of procuring, and enforcing, strong intellectual property rights."

LITIGATION

Distributor Enters Guilty Plea for Unapproved Development and Sale of Stem Cells

An Arizona woman who formerly owned a company that sold stem cells to clinics to treat patients with incurable autoimmune diseases, such as amyotrophic lateral sclerosis and multiple sclerosis, has entered a guilty plea to charges that she did so without meeting Food and Drug Administration (FDA) requirements. Fredda Branyon apparently purchased umbilical cords from a birthing facility in Texas, hired a South Carolina medical school professor to help her create stem cells from the tissue, and then sold the stem cells to a Texas medical clinic for use in the treatment of disease.

Because the stem cells were not created in an FDA-approved laboratory or under FDA guidelines, and because their use in treating patients was not approved by the FDA, Branyon was charged with introducing an unapproved new drug into interstate commerce in violation of the Food, Drug, and Cosmetic Act. According to the FDA, Branyon faces up to three years in prison and a fine of up to $10,000. A sentencing hearing has been scheduled for November 18, 2011. *See U.S. Department of Justice News Release*, August 18, 2011.

Federal Court Upholds Glaucoma Drug Patents and Enjoins Generics

A federal court in Texas has determined that four combination glaucoma drug patents held by Allergan Inc. were valid and that generic drug makers infringed the patents by seeking Food and Drug Administration (FDA) approval to sell their generic versions under an abbreviated new drug application. ***Allergan, Inc. v. Sandoz, Inc.*, No. 09-97 (U.S. Dist. Ct., E.D. Tex., Marshall Div., decided August 22, 2011)**. Allergan asserted in separate lawsuits that four generic drug makers infringed its patents, and they responded by contending that the patents were invalid due to obviousness in light of the prior art.

Consolidating the cases for resolution, the court determined that "there are significant differences between the prior art and the claimed inventions, such that a person of ordinary skill in the art would not have been motivated to create a fixed combination composition of 0.2% brimonidine and 0.5% timolol." In its detailed findings of fact and conclusions of law, the court

discusses the history of treating glaucoma, noting the difficulties patients had with side effects, the potential for allergy development and compliance with dosage requirements when dosing themselves with eye drops containing single-ingredient, glaucoma-drug formulations. The court also addresses the challenges Allergan faced developing a safe and effective combination product. The generics will be enjoined until Allergan's patents expire.

Anti-Nanotech Group Targets Researchers; Swiss Perpetrators Sentenced

A group known as "Individualities Tending Toward Savagery" (ITS) has reportedly claimed responsibility for injuring two Mexican nanotechnology researchers with a parcel bomb, putting scientists around the world on alert. According to an August 21, 2011, *Chronicle of Higher Education* article, the group has a manifesto that cites Ted Kaczynski, the Unabomber, as an inspiration and "has been linked to attacks in France, Spain, and Chile, and to a bomb sent earlier this year to a scientist at another Mexican university who specializes in nanotech." An analyst quoted by the *Chronicle* also warned that the threats "show signs of someone well-educated who could be affiliated with a college."

The latest attempt apparently targeted the director of a technology-transfer center at the Monterrey Institute of Technology and Higher Education, while an April 2011 bomb was intended for the nanotechnology department at the Polytechnic University of the Valley of Mexico. State of Mexico Attorney General Alfredo Castillo told media sources that the group may have terrorist ties in other countries, with the *Chronicle* adding that last month members of the ELF Switzerland Earth Liberation Front were sentenced for similar plots against a nanotechnology laboratory in Switzerland. "The ITS is a movement that, in accordance with its ideals, opposes any development of neo- or nanotechnology anywhere in the world," said Castillo, who has since urged Mexican universities to tighten security. *See The Associated Press,* August 9, 2011; *Times Union,* August 24, 2011.

NEWS BYTES

The U.S. Patent and Trademark Office and the Taiwan Intellectual Property Office establish a new pilot project for the Patent Prosecution Highway. Under the auspices of the American Institute of Taiwan and the Taipei Economic and Cultural Representative Office, the project will allow both offices to benefit from each other's previous work to reduce the patent examination workload and improve patent quality.

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UPCOMING CONFERENCES AND SEMINARS

The American Conference Institute will conduct a program, "Life Sciences Business Development & Acquisitions in Emerging Markets," scheduled for September 26-27, 2011, in New York City. Industry leaders will "share their recent hands-on experience in the evolving transactional environment," including developing business in "high-performing emerging countries."

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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.

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