Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

U.S. Supreme Court's Approach to Bayh-Dole Secures Inventors' Rights

The U.S. Supreme Court has determined that a federal law known as the Bayh-Dole Act does not displace the long-established rule that rights in an invention belong to the inventor and that title to federally funded inventions does not automatically vest in federal contractors. ***Bd. of Trustees of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, No. 09-1159 (U.S., decided June 6, 2011)**. Additional information about the case, which involves a patent dispute between a biotech company and a university researcher who worked on the technology, appears in Issues 2 and 9 of this *Bulletin*.

Shook, Hardy & Bacon Intellectual Property Partner **Peter Strand** has provided a **summary and analysis** of the Court's opinion as part of his monthly *IpQ* series of newsletters.

D.C. Meeting to Focus on Intellectual Property Issues Involving China

Shook, Hardy & Bacon Intellectual Property Attorney **Tom Moga** has been invited to a June 28, 2011, meeting in Washington, D.C., to discuss developments in innovation and intellectual property policy in China with representatives from the Congressional-Executive Commission on China, U.S. Chamber of Commerce and U.S. Patent & Trademark Office.

The meeting will focus on (i) the current status of U.S. government, academic and private sector efforts, "including recent concluded bilateral innovation dialogues, training programs of antitrust judges, IPR working groups, and how they relate to our knowledge and engagement on China's innovation strategies"; and (ii) recent and ongoing research, including reports undertaken by the National Bureau of Asian Research and U.S. International Trade Commission.

The discussion will help solidify an agenda and establish a working group for a forthcoming George Washington University program on indigenous innovation and intellectual property in China.

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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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NEW BIO BUSINESS VENTURES

Stem Cell Bank Joint Venture Forms in South Africa

Cryo-Save Group N.V., an international family stem cell bank, and John Daniel Holdings Ltd. (JDH), the controlling shareholder of Lazaron Biotechnologies, Africa's first private cord blood stem cell bank, have announced a new stem cell bank joint venture in South Africa. Operating under the name Cryo-Save South Africa, the venture will combine "Cryo-Save's leading expertise in stem cell processing and storage with JDH's local and African market expertise."

Expected to start before the end of July 2011, Cryo-Save South Africa will offer "customers the option of storing cord tissue and stem cells from cord blood in South Africa or off shore in Belgium." According to Cryo-Save, cord blood and cord tissue stem cells from the umbilical cords of newborn infants can be used in therapies for more than 70 diseases and for cosmetic and post-injury healing. *See Cryo-Save Press Release*, June 2, 2011.

INVESTOR NEWS

Ernst & Young Issues 25th Global Biotech Business Report

With research and development money growing increasingly scarce, Ernst & Young suggests in its latest ***Beyond Borders*** report that the traditional biotech business model may be under new pressures, but is still profitable. According to the report, companies in this sector operating in Australia, Canada, Europe, and the United States "had a record-breaking aggregate net profit of US$4.7 billion, a 30% increase from the previous year." Funding is skewed, however, with just 20 percent of U.S. biotechs garnering 82.6 percent of funding. And while the number of mergers and acquisitions slowed across the United States and Europe, Ernst & Young predicts that deals in the $1 billion to $5 billion range will likely be most attractive to drug companies.

Ernst & Young offers the following advice to biotech companies: (i) "Prove it or lose it." Companies must differentiate their products and "demonstrate comparative effectiveness for regulators," while being "willing to engage in creative pricing approaches for payers including outcomes-based pricing approaches." (ii) "Do more with less." Companies must creatively raise, optimize, preserve, and invest capital, "from new ways of monetizing existing intellectual property to pursuing 'virtual' company models to reduce fixed infrastructure." (iii) "Build new competencies." Managers must be aware of changing market dynamics and have the ability to measure and communicate value. They must also have "the creativity to develop new models and approaches." (iv) "Collaborate for coordinated action." Biotech companies must take coordinated action with other stakeholders, including "encouraging a system of adaptive clinical trials and conditional drug approvals; realigning

payment mechanisms around health outcomes; developing incentives to retain biotech investors; and working on transparency and access to build trust." *See The New York Times*, June 14, 2011.

Financial Group Analyzes M&A Deals in Biotech and Medical Device Industries

According to an SVP Financial Group **report**, contrary to conventional wisdom, biotech exits occur faster than device exits and have lower, but solid, multiples on invested capital. The study examined large, private merger and acquisition (M&A) exits of U.S. venture-backed life science companies between 2005 and 2010. The data set apparently included 60 biotech and 58 medical device deals. The report notes, "Biotech continues to see quick Big Exits from the close of Series A (5.05 years on average) with a solid 4.1X return. Device has taken longer over the last six years (7.01 years on average), but has a bigger average exit at 5.2X. Rudimentary gross IRR [internal rate of return] calculations show Big Exits in both areas are solid returners, with Biotech at about 34 percent IRR and Device at about 28 percent IRR."

Another study finding was a sharp increase in structured deals in the biotech industry since 2009. The report cites three main reasons for the increase: (i) deals that were "all-in exits failed in subsequent clinical trials or during FDA approval," leading acquirers to refuse to take all performance risk and to structure their deals by paying some upfront value "but waiting to pay out the majority of the transaction value until the asset completed milestones that advanced it deeper into the clinic"; (ii) a perceived weakness in venture capital's ability to support companies with sufficient capital to "get through the next expensive and/or lengthy trial" apparently provides the acquirer with an advantageous bargaining position; and (iii) "[l]icensing deals have quickly morphed into M&A discussions as acquirers realize that many investors will accept smaller (and more importantly, quicker) realizations upfront with some performance upside."

$15 Million to Boost Constellation Pharmaceuticals' Product Development

Massachusetts-based Constellation Pharmaceuticals has announced that it has raised $15 million in a Series B extension financing that will help it "continue to advance product candidates in its portfolio toward clinical development." Working in the epigenetics field, the biopharmaceutical company is "focused on the discovery and development of small molecule therapeutics against chromatin-based targets to treat cancer and inflammatory/immunologic disorders." All major current investors reportedly participated in the financing round. *See Constellation Pharmaceuticals Press Release,* June 6, 2011.

Biotech Raises $9.2 Million for Oncology Prodrug Development

San Francisco-based Cyterix Pharmaceuticals, Inc. has announced that it has raised $9.2 million in a Series A financing from The Colum Group and

SV Life Sciences. In developing drugs which target certain enzymes that are over-expressed in many cancers, Cyterix's goal is discovering and developing "multiple classes of small molecule oncology prodrugs with a superior safety and efficacy profile to classical cytotoxic and molecularly targeted agents." The company will expand its exploration of "new targets within the extra-hepatic cytochrome P450 enzyme family" with the funds. *See Cyterix Pharmaceuticals Press Release,* June 7, 2011.

Biopharmaceutical Will Use Series B Financing to Advance MRSA Antibody

Biopharmaceutical Excelimmune has announced the final closing of a $10.5 million Series B financing that will "advance Staphguard, a human recombinant polyclonal antibody (HRPA) candidate against methicillin-resistant Staphylococcus aureus (MRSA)." The Massachusetts-based company claims that a preclinical study presented at the 50th Interscience Conference on Antimicrobial Agents and Chemotherapy showed that "at a[n] MRSA dose 100 percent lethal in the control group, the group treated with Staphguard experienced 100 percent survival."

According to Excelimmune CEO Quinton Zondervan, the funding doubled the company's size over the past year and provided it with capital for next-stage product and technology development. "The continued support from investors underscores the significant potential of our unique HRPA approach to treating nosocomial infectious disease," he said. *See Excelimmune Press Release,* May 31, 2011.

BUSINESS CLIMATE

Physician Explores Future of Whole Genome Sequencing

"The iconic $1,000 genome is very close to a reality—at least in terms of reagent costs," writes Eleanor Herriman, director of G2 Research and Analysis with Kennedy Information Inc., in a June 3, 2011, article for BNA's *Life Sciences Law & Industry Report*. "It seems timely, then, to check in on whole genome screening (WGS), a technique predicted to significantly affect personalized therapeutics, diagnostics, clinical medicine, and even consumer behavior."

Titled "Whole Genome Sequencing: A 'PC-Like' Revolution for Medicine, Pharmaceuticals, and Society?," the article compares the personal computer revolution to the DNA sequencer market, which "deserves attention and consideration soon, because the exponential trajectory it will follow will leave those who wait far behind."

Exponential leaps in sequencing have "brought us so rapidly to the brink of an inexpensive, widely available WGS tool," Herriman asserts, quoting statistics such as "approximately 25,000 genomes will be sequenced in 2011, including

low-coverage genomes." Claiming that WGS "is on the brink of breaking through a number of barriers and advancing at warp speed," Herriman concludes, "it is not often that we participate in technologic evolutions of this magnitude. Pharmaceutical and biotech companies that delve deeply into this movement, and stay close to the innovators, will be well positioned to capture some hitherto unimaginable opportunities in coming years."

LEGISLATIVE AND REGULATORY DEVELOPMENTS

U.S. Patent Reform Hits Snag

House Appropriations Committee members have opposed a provision in patent reform legislation that would allow the U.S. Patent & Trademark Office (USPTO) to keep the application fees it collects. In a June 7, 2011, letter to House Majority Leader Eric Cantor (R-Va.), four committee members contend that allowing the patent office to keep the fees "undermines efforts to strengthen oversight and accountability of the PTO as well as efforts to ensure resources are being used wisely and appropriately."

Recently passed by the House Judiciary Committee, the America Invents Act is expected to come before the full House soon; it is endorsed by the Obama administration, which called the measure the most meaningful patent reform in 60 years. The House bill closely resembles legislation overwhelmingly approved by the Senate earlier this year.

Those in favor of the USPTO keeping application fees argue that the agency needs the money to tackle the backlog of more than 1 million pending patent applications. "These are products and innovations that can grow businesses, create jobs and save lives," said House Judiciary Chair and bill sponsor Lamar Smith (R-Texas). "Allowing the PTO to retain the fees it collects means more patent examiners to help get products to the market faster." *See The Hill,* June 9, 2011.

ITC Report on IP Rights in China Cites SHB Article

Shook, Hardy & Bacon Intellectual Property Attorney Tom Moga has been cited in the U.S. International Trade Commission's (ITC's) May 2011 report on intellectual property rights (IPR) and indigenous innovation policies in China, and how they affect the U.S. economy and employment.

According to the commission, many U.S. businesses have reported losses "associated with IPR infringement in China, including losses in sales, profits, and license and royalty fees, as well as damage to brand names and product reputation," and registered concern over the future implications of China's indigenous innovation policies.

To this end, the ITC report aims to quantify (i) "the estimated size and scope of IPR infringement in China, as reported by U.S. IP-intensive firms"; (ii) "the potential effects of a substantial improvement in IPR protection in China on the U.S. economy and employment, as a measurable proxy for the economic effects associated with IPR infringement in China on the U.S. economy and employment"; and (iii) "the U.S. economic effects resulting from China's indigenous innovation policies."

During the report's preparation, Moga met with ITC economist Kate Litton to discuss technology transfer and research and development requirements pertaining to China's automotive joint ventures. The final report specifically references "Tech Transfer Turning Point?," an article Moga authored in the September-October 2010 edition of *China Business Review,* in addressing "the relatively low royalty rates offered by Chinese companies for access to new technology."

FDA Releases Nanotechnology Guidance for Regulated Industries

The U.S. Food and Drug Administration (FDA) has released draft guidance describing "the agency's view on whether regulated products contain nanomaterials or involve the application of nanotechnology." Published in conjunction with a June 9, 2011, nanotechnology memorandum authored by the Office of Science and Technology Policy, Office of Management and Budget, and U.S. Trade Representative, the FDA guidance aims "to provide regulated industries with greater certainty about the use of nanotechnology" and names "certain characteristics—such as the size of nanomaterials used and the exhibited properties of those materials—that may be considered when attempting to identify applications of nanotechnology in regulated products."

Once finalized, the guidance will help FDA better understand the properties and behavior of engineered nanomaterials, and assist manufacturers early in the development process "so questions related to the regulatory status, safety, effectiveness or public health impact of these products can be adequately addressed." The agency will accept public comments on the draft document for 60 days after publication in the *Federal Register.*

Is FTC Considering Fast-Track Rulemaking to Stop "Pay-for-Delay" Drug Deals?

According to a news source, the Federal Trade Commission (FTC) may be planning to adopt a rule under expedited procedures to block patent settlements, known as "pay-for-delay" deals, between name-brand drug manufacturers and generic drug makers. Such deals are evidently reached when generic drug makers are paid to drop the patent lawsuits they file hoping to get their products to market more quickly. Citing unnamed sources, *Bloomberg.com* said that the rulemaking route is under consideration because the agency's

efforts to block the deals in court have failed and Congress has not taken action to make them illegal. While FTC spokesperson Peter Kaplan noted that the agency's strategy is to fight the deals in court and seek legislation, he also said, "We are not dismissing any option out of hand." *See Bloomberg.com*, June 9, 2011.

FDA Seizes Probiotic Products Marketed as Drugs

The Food and Drug Administration (FDA) has reportedly seized probiotic products from a Minnesota-based company, alleging that they are being marketed as drugs. UAS Laboratories, Inc. apparently claims that its dietary supplements "could treat or prevent colds, flu, respiratory infections, urinary tract infections, yeast infections, ulcers, and high cholesterol." The agency previously warned the company that it was violating the law and found during a March 2011 inspection that the company continued to make these claims. According to FDA, the products are misbranded under the Federal Food, Drug, and Cosmetic Act because the labeling fails to include adequate directions for use. FDA also alleges that the company did not seek its approval under a new drug application process. *See FDA News Release*, June 7, 2011.

Commercial Airlines Receive Preliminary Approval to Use Bio-Based Fuel

The ASTM International Committee on Petroleum Products and Lubricants has reportedly given preliminary approval to the use by airlines of a new jet fuel that blends traditional fuel with biofuel from organic waste and inedible plants. The U.S.-based technical standards development group's action was applauded by the Air Transport Association of America (ATA) for enabling further use of "sustainable alternative fuels in aviation."

According to a news source, final ASTM approval is expected no earlier than July 1, 2011, with airlines able to use the biofuel soon thereafter. Referred to as "Hydro-processed Esters and Fatty Acids" (HEFA) fuel, the biofuel consists of biomass feedstocks such as camelina, jatropha and algae. Revised ASTM jet-fuel specifications will allow a blend of up to 50 percent HEFA fuel in conventional jet fuel.

"The real winners of this type of regulatory breakthrough will be technology companies involved in the production of aviation biofuels," said Harry Boyle, a Bloomberg New Energy Finance analyst. "The biotech-biofuels business models of Amyris Inc. (AMRS), Codexis Inc. (CDSX), Gevo Inc. and Solazyme Inc. are all making claims to these types of new markets." Other companies possibly benefitting from the $139-billion-a-year aviation fuel market reportedly include Finland's Neste Oil Oyj, Spain's Abengoa SA, and Honeywell International Inc.

"Developing a renewable fuel supply is a critical part of our industry's strategy for achieving carbon-neutral growth beyond 2020 and creating a sustainable future for aviation in the global community it serves," a Boeing official reportedly said. *See Bloomberg,* June 9, 2011; *ATA Press Release,* June 10, 2011.

LITIGATION

Review Denied on Failed Challenge to Stem Cell Research Funding Order

The U.S. Supreme Court has reportedly denied a petition asking it to review a Fourth Circuit Court of Appeals ruling that human embryos and those considering adopting human embryos lack standing to challenge President Barack Obama's executive order removing restrictions on funding for embryonic stem cell research. *Doe v. Obama*, No. 10-1206 (U.S., *cert.* denied May 31, 2011). The lower courts determined that the plaintiffs failed to allege particularized and imminent injury fairly traceable to the executive order and implementing regulations. Additional details about the Fourth Circuit's ruling appear in Issue 6 of this *Bulletin. See BNA Life Sciences Law & Industry Report*, June 3, 2011.

U.S. Supreme Court Adopts "Willful Blindness" Standard for Inducement of Infringement

In an 8-1 ruling, the U.S. Supreme Court has determined that the doctrine of willful blindness can be used to establish liability for actively inducing the infringement of a patent. ***Global-Tech Appliances, Inc. v. SEB S.A.* No. 10-6 (U.S., decided May 31, 2011)**. The issue arose in a case involving a design patent for a deep fryer. The alleged infringer claimed that it did not learn about the relevant patent until it received notice of the infringement lawsuit filed against the company (Sunbeam) for which the fryer was designed, and, thus, the jury lacked sufficient evidence to find induced infringement. Two lower courts rejected that argument, with the Federal Circuit Court of Appeals determining that the evidence showed "Pentalpha deliberately disregarded a known risk that SEB had a protective patent," and that this disregard "is a form of actual knowledge."

The U.S. Supreme Court affirmed the Federal Circuit's decision but rejected the "deliberate indifference" standard, ruling that "the evidence in this case was plainly sufficient to support a finding of Pentalpha's knowledge under the doctrine of willful blindness." As formulated by the Court, this doctrine, which "surpasses recklessness and negligence," requires a showing that a defendant took "deliberate actions to avoid confirming a high probability of wrongdoing" and "can almost be said to have actually known the critical facts." Here, the defendant copied an overseas model of the plaintiff's fryer, which model lacked U.S. patent markings, for sale in the United States and did not inform the attorney asked for a right-to-use opinion that the product to be evaluated was a knockoff.

According to Justice Samuel Alito, writing for the majority, "Taken together, this evidence was more than sufficient for a jury to find that Pentalpha subjectively believed there was a high probability that SEB's fryer was patented, that Pentalpha took deliberate steps to avoid knowing that fact, and that it

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therefore willfully blinded itself to the infringing nature of Sunbeam's sales."

Dissenting Justice Anthony Kennedy was concerned that the Court's adoption of the willful blindness doctrine in this civil case would have significant ramifications for any alleged knowledge-based criminal offense.

NEWS BYTES

The Food and Drug Administration (FDA) announces the availability of guidance for industry and investigators on the enforcement of safety reporting requirements for investigational new drug applications and bioavailability/bioequivalence studies.

FDA issues for comment draft guidance titled "Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators."

Fourteen federal district courts in California, Florida, Illinois, Maryland, Nevada, New Jersey, New York, Pennsylvania, Tennessee, and Texas have been selected to participate in a 10-year pilot project designed to enhance expertise in patent cases among U.S. district judges.

UPCOMING CONFERENCES AND SEMINARS

The Biotechnology Industry Organization's 2011 International Conference is scheduled for June 27-30 in Washington, D.C. More than 15,000 are expected to participate in the event, which will include an exhibition, business forum and biotechnology program sessions.

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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.

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.