Shook, Hardy & Bacon L.L.P.

ISSUE 1 | OCTOBER 21, 2010

BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Biotech Trade Group Seeks USDA Involvement in Gene Patents Lawsuit

The Biotechnology Industry Organization (BIO) has asked U.S. Department of Agriculture (USDA) Secretary Tom Vilsack to urge the Department of Justice, which is considering the federal government's position in litigation about patent protection for isolated DNA sequences, to "strongly defend the patentability of such basic biotech inventions." In a lawsuit filed by the American Civil Liberties Union against a genetic diagnostic testing company, a federal district court has apparently determined that this material is not eligible for patent protection because it is derived from natural sources. According to the trade group's letter, "the patented DNA molecules [at issue in the litigation] are important for clinical breast cancer testing—but the reasoning of the district court was so expansive that patents on animal, plant, bacterial or viral DNA preparations are now also in serious question."

The case has been appealed to the Federal Circuit Court of Appeals; BIO notes that industry is uncertain "whether DOJ has sufficiently appreciated the implications of the case outside of the human clinical diagnostics area." BIO contends that a negative outcome "would greatly and negatively impact our ability to meet the nutritional demands of an ever increasing world population, to mitigate harmful impacts of global climate change, and to reinvigorate the American economy through agriculture." The organization also claims that patent protection is crucial "for the hundreds of small biotech start-ups on the cutting edge of biotechnology innovation." *See Biotech NOW*, September 27, 2010.

JOINT VENTURE NEWS

Three-Year Collaboration to Create Synthetic Seed Virus Bank for Influenza Shots

Novartis AG and Synthetic Genomics Vaccines, Inc. have apparently agreed to collaborate on a project that is intended to reduce the time needed to develop influenza vaccines. Supported by the U.S. Biomedical Advanced Research and Development Authority, the three-year collaboration will create

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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.

For additional information on SHB's Biotechnology and Life Sciences capabilities, please contact

Patrick Henderson
Corporate Transactions
816-559-2115
phenderson@shb.com

Madeleine McDonough
Pharmaceuticals & Medical Device
202-783-8400
mmcdonough@shb.com

Thomas Moga
Intellectual Property
202-639-5622
tmoga@shb.com

If you have questions about this issue of the Report, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

seed viruses, or the templates from which vaccines are created, relying on Synthetic Genomics technology. According to a news source, companies that manufacture vaccines rely on the World Health Organization (WHO) to identify and distribute live reference viruses to develop seasonal or pandemic vaccines. As soon as WHO identifies the flu strain active in any given year, the companies hope to have synthetic seed viruses ready to go into production. Synthetic Genomics is run by Craig Venter, best known for his competitive efforts to decode the entire human genetic blueprint in 2000. *See Bloomberg*, October 7, 2010.

INVESTOR NEWS

Energy Interests and Investors Concerned About New Derivatives Regulation

While European and U.S. regulators develop new rules to govern derivative transactions, energy companies and investors are reportedly expressing concerns about the potential for measures that are intended to rein in the risks taken by financial institutions to affect their business. The energy industry apparently relies on derivatives and hedging as a buffer against fluctuating commodity prices and to guard against risk over the life of a loan on major projects. Industrial and commercial energy users also use hedging as protection against changes in fuel and power prices.

The New York Times reports that the Commodity Futures Trading Commission has been releasing its new regulations under the Dodd-Frank Wall Street Reform and Consumer Protection Act piecemeal, which has made gauging their impact difficult. According to risk managers, if credit is more difficult to obtain and less market liquidity ensues, the ability of companies to invest in facilities, storage and infrastructure will be affected. Public comment is requested on commission proposals, but industry watchers apparently believe they will remain, for the most part, intact. *See The New York Times*, October 13, 2010.

Macro-Algae Attracting Millions in Government and Industry Financing

According to news reports, macro-algae, or seaweed, is being viewed by major investors as a better source of sugars for ethanol, biofuels, biochemicals, and biopolymers than land-based crops, because it grows faster, has a higher sugar content, absorbs more airborne carbon, and can be harvested up to six times each year. Among those entities investing millions in macro-algae production and research are South Korea, the city of Venice, Scotland, Chile, the Philippines, the U.S. Department of Energy, and companies such as DuPont and Bio Architecture Lab. China and other Asian nations have apparently used macro-algae for more than 100 years for food, animal feed, pharmaceuticals, and cosmetics. Its emergence and future in biofuels

commercialization is analyzed in detail in *Algae 2020*. *See Biofuels Digest*, October 4, 2010.

Meanwhile, *CNN.com* has reported that the airline industry is investing in research on harvesting algae for jet fuel. British Airways and Airbus are apparently supporting Cranfield University researchers who believe algae could be produced commercially within four years. According to Cranfield Professor Feargal Brennan, "A great advantage of algae is you can harvest it every seven to 12 days, so you get 30 to 50 harvests a year, compared with one a year of conventional crops." Part of the research includes investigating whether algae could be grown in close proximity to airports to avoid transportation costs and reduce carbon footprint. *See CNN.com*, October 11, 2010.

BIO Investor Forum Sessions Focus on Reinventing the Biotech Business Model

Acknowledging a difficult capital formation and financing climate, speakers at the recent BIO Investor Forum in San Francisco reportedly contended that strong science will prevail regardless and creative approaches to financing will help move promising technologies forward. By exploring recent successful ventures, forum participants apparently learned how deals involving related biotech innovations with multiple potential uses can attract significant financial backing. While investment returns have not been strong in recent years and investors are more interested in later stage assets, opportunities exist for those planning carefully and efficiently. Some speakers reportedly expect more venture arms in the future among large pharmaceutical and biotech companies and more deals generated in this arena. *See BIOtechNow*, October 6, 2010.

BUSINESS CLIMATE

University Start-Ups and Licensing Remain Strong

The Association of University Technology Managers (AUTM) has reportedly announced that university start-ups and licensing activity were unaffected at the height of the recession in 2009. AUTM's fiscal year (FY) 2009 survey found that 569 new companies were formed as a result of university research, one more than those created in FY 2008. While licensing revenue reportedly declined 32.5 percent, AUTM apparently attributed the drop to extraordinary partial royalty buyouts in 2007 and 2008 that were not repeated in 2009. The number of licenses apparently increased 5.6 percent in FY 2009. According to AUTM President Ashley Stevens, the survey results reveal "that universities were able to maintain their level of start-up company creation [in 2009]," and noted, "[t]he majority of these start-ups are located in the licensing institution's home state . . . further proof that the Bayh-Dole Act continues to have a positive impact on local economies." *See PatentDocs.org*, October 7, 2010.

In a related development, the National Research Council reports that the Bayh-Dole Act, which changed the law to allow universities to retain ownership of intellectual property developed under grants from federal agencies, has effectively made research advances publicly available and spurred innovation. Before the law was enacted in 1980, the government owned the intellectual property it funded and could license it to companies for use in new products and services. According to the report, very little federally funded research was commercialized. Since 1980, however, patenting and licensing activity has apparently accelerated. Still, the report recommends improving the current system by standardizing licensing contracts, creating independent oversight of relationships between faculty and university technology transfer offices and developing mechanisms for resolving disputes when faculty believe their inventions are being ignored or mishandled. *See National Academies Press Release*, October 4, 2010.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

HHS Issues Guidance for Gene and Genome Synthesis Industry

The Department of Health and Human Services (HHS) has issued a guidance document with recommended baseline standards for companies providing synthetic double-stranded DNA (dsDNA) to effectively screen orders so they comply with U.S. regulations and encourage best practices in addressing biosecurity concerns associated with potential misuse of their products.

Titled "Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA," the document is intended to "reduce the risk that individuals with ill intent may exploit the application of nucleic acid synthesis technology to obtain genetic material derived from or encoding Select Agents or Toxins and, as applicable, agents on the Export Administration Regulations' (EAR's) Commerce Control List (CCL)."

The screening framework protocols, which became effective October 13, 2010, consist of customer screening, sequence screening and follow-up screening. Customer screening involves customer verification and the identification of any "red flags"; sequence screening, "which identifies whether a requested sequence is a 'sequence of concern,' is intended to serve as a trigger for further follow-up screening and does not by itself provide a basis for determining whether an order poses a risk. Providers should screen all orders of dsDNA." According to HHS, follow-up screening aims to "verify the legitimacy of the customer and principal user, to confirm that the customer and principal user placing an order are acting within their authority, and to verify the legitimacy of the end-use." *See Federal Register*, October 13, 2010.

FDA Publishes Final Rule on Investigational New Drug Applications, Issues Draft Guidance

The Food and Drug Administration (FDA) has **issued** a final rule that amends its "regulations governing safety reporting requirements for human drug and biological products subject to an investigational new drug application (IND)." Titled "Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans," the new rule is effective March 28, 2011. When it issued the rule, the agency also published a **draft guidance document** to assist "sponsors and investigators" required to comply with the rule. FDA requests comments on the guidance by December 28, 2010.

Among other matters, the rule now provides definitions for "adverse event," "life-threatening adverse event," "serious adverse event," "suspected adverse event," and "unexpected adverse event." The rule also clarifies how and when to submit IND safety reports to FDA, clarifies "the sources of information that sponsors must review for safety surveillance and reporting purposes," and makes "bioavailability and bioequivalence studies subject to IND safety reporting requirements." *See Federal Register*, September 29, 2010.

Public Hearing Scheduled on Implementing Biosimilars Legislation

FDA has **announced** that it will conduct a two-day hearing for stakeholders to provide input on the agency's implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCI). The BPCI establishes "an abbreviated approval pathway for biological products that are demonstrated to be 'highly similar' (biosimilar) to, or 'interchangeable' with, an FDA-licensed biological product."

Scheduled for November 2-3, 2010, the hearing is designed to gather public input on issues such as (i) "scientific and technical factors related to a determination of biosimilarity or interchangeability," (ii) "the type of information that may be used to support a determination of biosimilarity or interchangeability, (iii) "development of a framework for optimal pharmacovigilance for biosimilar and interchangeable biological products," (iv) "scope of the revised definition of a 'biological product,'" (v) "priorities for guidance development," (vi) "scientific and technical factors related to reference product exclusivity," (vii) "scientific and technical factors that may inform the agency's interpretation of 'product class' as it relates to available regulatory pathways for certain protein products during the 10-year transition period following enactment of the BPCI Act," and (viii) "the establishment of a user fee program for biosimilar and interchangeable biological products." *See The Hill*, September 20, 2010; *FDA News & Events*, October 4, 2010; *Federal Register*, October 5, 2010.

LITIGATION

GeneScience Pleads Guilty to Charges of Selling Human Growth Hormone in U.S.

GeneScience Pharmaceutical Co., Ltd. and its CEO have pleaded guilty to selling Jintropin, a human growth hormone used to build muscle, without the approval of the Food and Drug Administration. *U.S. v. GeneScience Pharmaceutical, Co., Ltd.*, No. 10-144-02 (U.S. Dist. Ct., D.R.I., plea entered October 1, 2010). The defendants agreed to pay $4.5 million as a substitute asset to satisfy the forfeiture allegations of the criminal information and will contribute $3 million to create a "Clean Competition Fund" to satisfy a community service obligation. CEO Jin Lei was sentenced to five years' probation and will not be permitted to sell drugs to U.S. customers during that time without the approval of the Department of Health and Human Services. According to a news source, GeneScience is believed to be responsible for most of the human growth hormone smuggled into the United States. *See The Associated Press,* October 7, 2010.

Life Sciences on U.S. Supreme Court 2010-2011 Docket

Among other closely watched cases currently pending before the U.S. Supreme Court is ***Bruesewitz v. Wyeth, Inc.*, No. 09-152**.

At issue is the scope of the express preemption provision in the National Childhood Vaccine Injury Act of 1986, which created a federal compensation program for those allegedly injured by vaccination side effects. The petitioners challenge a Third Circuit Court of Appeals interpretation that the law preempts all vaccine design defect claims, whether the vaccine's side effects were unavoidable or not. Section 22(b)(1) provides that certain design defect claims cannot be brought against vaccine manufacturers "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."

Argued on October 12, 2010, the case apparently divided the justices some of whom were concerned that allowing lawsuits against drug makers outside the compensation system could cripple the industry. Other justices reportedly suggested that vaccine manufacturers might have no incentive to produce the safest possible vaccines if the vaccine court is the only recourse for "vaccine victims." Justice Elena Kagan did not participate in oral argument; she recused herself because as solicitor general she urged the Court to grant review in *Bruesewitz*. Chief Justice John Roberts initially recused himself from hearing the case because he owned Wyeth stock, but has since sold the stock and rejoined the case. If the Court splits 4-4 over the matter, the Third Circuit ruling in Wyeth's favor will stand. *See Law.com*, October 13, 2010.

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NEWS BYTES

Ernst & Young reports that the U.S. biotechnology sector, an $87.9 billion industry, was profitable last year, the first time this has happened since the industry was created more than 30 years ago.

International researchers release GM soy report, challenging industry claims that technology is safe and sustainable.

Sixth Circuit strikes parts of Ohio regulation restricting hormone-free labeling on dairy products, finding First Amendment violations.

Federal court determines that plaintiffs are likely to succeed on merits of challenge to Animal and Plant Health Inspection Service GM sugar beet permits, setting briefing and hearing on remedies.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
London, England
+44-207-332-4500
Washington, D.C.
+1-202-783-8400
San Francisco, California
+1-415-544-1900
Irvine, California
+1-949-475-1500
Houston, Texas
+1-713-227-8008
Kansas City, Missouri
+1-816-474-6550
Miami, Florida
+1-305-358-5171
Tampa, Florida
+1-813-202-7100

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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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