Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Manhattan Institute Issues Report on "Patent Troll" Litigation

With recommendations to reform the legal system to curtail litigation brought by non-practicing entities (NPEs, also referred to as "patent trolls," or more narrowly, "patent assertion entities"), the Manhattan Institute's Center for Legal Policy has issued a **report** in its Trial Lawyers, Inc. series discussing how NPE litigation has increased 526 percent in six years at a direct cost of $29 billion in 2011, up from $7 billion in 2005. The report identifies the attorneys and companies that have profited by buying patents with the sole purpose of bringing infringement suits and coercing licenses from companies allegedly employing "downstream end uses of patented technologies," such as Wi-Fi and one-button-scan-and-send technology.

The institute recommends that steps be taken to limit the forum shopping that has landed a large percentage of these suits in a single federal district in Texas or before the International Trade Commission (ITC) and to adopt "loser pays" mechanisms that could rein in "nuisance" litigation typically won by defendants (at a 90-percent rate nationwide) when taken to trial. According to the report, defending such litigation can be costly. The institute also supports an Obama administration proposal that would bring the ITC's injunctive-relief standard in line with the standard applied by the U.S. Supreme Court in *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

INVESTOR NEWS

Regenerative Medicine Company Announces $18-Million Offering

AxoGen, Inc. an Alachua, Florida-based developer of peripheral nerve reconstruction and regeneration therapies, has priced an underwritten offering of 6-million shares of common stock at $3 per share with the goal of raising $18 million to expand commercialization and marketing efforts for its peripheral nerve repair products—Avance® Nerve Graft, AxoGuard®

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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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Nerve Connector and AxoGuard® Nerve Protector. In connection with the offering, AxoGen has received approval to list its common stock on the NASDAQ Capital Market, which, according to a news source, was part of the company's strategic plan to boost institutional action in its stock. "We have been looking at this and doing what we needed to do" to position the company in a more attractive trading market, according to AxoGen CFO Greg Freitag.

AxoGen reported steady quarter-over-quarter growth during 2012 and reportedly expects to exceed $12 million in revenue in 2013. "We believe that the market in the U.S. for the portfolio for nerve repair is around $1.6 billion," said Freitag. "We don't have to do anything else, other than keep selling this portfolio." Although the company's Avance® Nerve Graft is evidently approved in several European countries, the new financing is expected to boost the company's U.S. marketing efforts. *See AxoGen, Inc. News Release,* August 9, 2013; *bioworld.com,* August 12, 2013.

Intrexon Raises $160 Million in IPO for R&D

Germantown, Maryland-based life sciences company Intrexon has reportedly raised $160 million in its initial public offering (IPO). Initially priced at $16 per share, the stock closed nearly 55 percent higher, at $24.73. According to a news source, Chair and CEO Randal Kirk has agreed to purchase $30 million worth—or 1,875,000 of the 9,999,999 shares that were offered.

Intrexon, which collaborates with companies in the medical, animal science and agriculture sectors to engineer biological products and processes, reportedly plans to use the offering proceeds to invest in research and development (R&D). *See washingtonpost.com,* August 8, 2013.

Wellcome Trust Awards $2-Million Grant for Infant Gut Bacteria Research

The Wellcome Trust, an international charity that supports biomedical research, has awarded $2 million to Lindsay Hall, a researcher at the University of East Anglia and the U.K.'s Institute of Food Research. Known as the "New Investigator Award," the competitive funding program aims to "support strong researchers who are in the early stages of their independent research careers and have already shown that they can innovate and drive advances in their field of study."

Hall's award will fund a five-year research project into infant gut bacteria communities and how these establish within the gut and protect the body from infection. The study will also examine how antibiotics disturb this microbial community and whether their use increases the risk of infection later in life. The project will investigate new "probiotic" bacteria to restore

the microbial community and the ability to fight infection. Although antibiotics' role in long-term health is frequently researched in adults, few studies have evidently focused on their effects early in life.

"When we are born our gut is completely free of bacteria. Early life is when the colonisation of the gut by microbes starts but exactly how and why this happens isn't completely understood yet. This grant will help carry out vital investigations into how certain bacteria come to be present in the gut, the long-term results of using antibiotics, and if there is a better solution to treat infectious diseases like bacterial gastroenteritis," said Hall. *See Institute for Food Research News Release* and *eurekalert,* August 7, 2013.

Equity Fund Manager Raises $107 Million for Investment in Med-Tech Companies

Minneapolis-based SightLine Partners has reportedly exceeded its original $100-million target, closing its oversubscribed SightLine Healthcare Opportunity Fund II, L.P. at $107 million. The fund will apparently be dedicated to secondary direct investments in medical-technology companies. SightLine Partners manages private equity funds that provide "financing solutions to later stage medical device and diagnostic companies and financial alternatives to the existing investors in these companies." *See Business Wire*, August 8, 2013.

Interventional Microscope Maker Closes $4.8-Million Funding Round

Xlumena, Inc., which makes ultrasound-guided interventional microscopes, has closed a $4.8-million debt and securities round with 10 unnamed investors, according to a Securities and Exchange Commission filing. The Mountain View, California-based company has secured Food and Drug Administration approval for a pancreatic cyst access device and is reportedly concluding clinical trials that will support its 501(k) application for a stent and delivery system that will also treat pancreatic cysts. *See Mass Device*, August 9, 2013.

BUSINESS CLIMATE

Biotech Licenses, M&A and JV Deals Join IPO Surge in 2013

According to data analyzed by Recap, acquired by Thomson Reuters in June 2013, life sciences deals have surged in the first six months of the year, increasing 39 percent over the comparable 2012 period. More than 1,200 life sciences deals occurred between January and June, with licenses and joint ventures (JVs) representing 30 percent of the total, and mergers and acquisitions (M&As) representing 12 percent of the volume with dollar

values skewed toward M&As, at $52.6 billion—or 72 percent—of the total. Licensing and JV deals through June, on an upward trend since the fourth quarter of 2012, suggest that this activity will far outpace 2012, when 565 deals were recorded, down from 662 in 2011. Disclosed deal values, however, are lower in 2013 than the previous two years, at some $4.7 billion per quarter compared with average aggregate values of $5.8 billion per quarter in 2012 and $7.8 billion per quarter in 2011.

By market segment, Recap reportedly found that cancer dominated the licensing deals (36 percent), followed by neurology/central nervous system (15 percent), infectious disease (10 percent), autoimmune/inflammatory (9 percent), and endocrine/metabolic (6 percent). Therapeutic products apparently took the lead among M&As in the first half of 2013, representing 80 percent of the total disclosed M&A deal value of $52.6 billion. Diversified and broad-focus companies reportedly predominated as to total and average M&A deal sizes, displacing cancer from the top five therapeutic areas "for the first time in quite awhile." *See bioworld.com*, August 7, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FDA Issues Guidance on Clinical Investigations

The U.S. Food and Drug Administration (FDA) has issued draft **guidance** intended to enhance human subject protection and the quality of clinical trial data by focusing sponsor oversight on the most important aspects of study conduct and reporting. Titled "Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring," the guidance (i) "assists sponsors in developing risk-based monitoring strategies and plans for clinical investigations of human drugs, biologics, medical devices, and combinations thereof"; and (ii) "clarifies that sponsors can use a variety of approaches to meet their responsibilities for monitoring investigational new drug or investigational device exemption studies." *See Federal Register,* August 7, 2013.

Texas Compounder Agrees to Nationwide Recall of All Sterile Products

According to the U.S. Food and Drug Administration (FDA), Cedar Park, Texas-based compounding pharmacy Specialty Compounding LLC has agreed to recall all of its sterile products distributed in the United States since May 9, 2013. FDA noted that 15 people using the company's calcium gluconate infusions, often used to treat conditions associated with depressed calcium levels, developed bacterial bloodstream infections potentially related to the treatment. Sen. Tom Harkin (D-Iowa) responded

to the announcement by calling attention to pending legislation that would increase FDA oversight of compounding pharmacies that develop sterile products without a prescription and sell them across state lines. He said, "The Senate has before it a unique opportunity to take bipartisan action and improve the safety of compounded drugs." *See CQ Healthbeat News*, August 12, 2013.

LITIGATION

Ambry Genetics Countersues Myriad Genetics in Genetic Patent Infringement Suit

Responding to the patent infringement claims asserted against it by Myriad Genetics, Ambry Genetics Corp. denies that the 15 patents at issue were duly and legally issued by the U.S. Patent and Trademark Office and counterclaims seeking a declaratory judgment that the patents are invalid and not infringed and that Myriad has violated U.S. antitrust laws through bad faith enforcement of these patents. *Univ. of Utah Research Found. v. Ambry Genetics Corp.*, No. 13-0640 (U.S. Dist. Ct., D. Utah, Cent. Div., counterclaims filed August 5, 2013). Additional details about the lawsuit appear in Issue 60 of this *Bulletin*.

In an apparent effort to counter Myriad's claim that it invested $500 million and extensive efforts to develop its breast cancer tests by identifying genetic mutations, Ambry recites the parallel and collaborative efforts undertaken by national and international teams of researchers, with significant levels of government funding, to find ways other than radical surgery to address what is termed a "breast cancer epidemic." It alleges that Myriad hoarded information that should be publicly available, improperly sought to patent isolated gene sequences that were patent-ineligible, and aggressively commercialized its discoveries, by, among other matters, litigating to keep competitors out of the marketplace. Ambry also discusses the court rulings that culminated in the U.S. Supreme Court's June 2013 determination that certain of Myriad's claims were not patent eligible, stating, "Myriad is wrongfully attempting to enforce claims that have common subject matter to the invalidated claims in defiance of the Supreme Court's opinion." The Court's opinion is summarized in Issue 59 of this *Bulletin*.

The counterclaim further contends that Myriad has falsely informed genetic counselors that Ambry's tests infringe Myriad's patents and they produce unreliable results. Ambry also claims that Myriad urges the counselors not to send their samples to Ambry for testing, "misrepresenting that Ambry will bill the patient the balance of any difference between

the retail price of Ambry's test and the price negotiated with the insurer." Alleging violation of the Sherman Act, through exclusionary and anticompetitive conduct and attempted monopolization, Ambry seeks to enjoin Myriad under the Clayton Act from enforcing the patents, which it asks the court to declare invalid. Ambry requests damages, triple damages, interest, attorney's fees, and costs.

Myriad has reportedly responded that its claims will prevail and stated, "The testing process employed by Ambry infringes 10 patents covering synthetic primers, probes, and arrays, as well as methods of testing related to the BRCA1 and BRCA2 genes. The claims at issue in this case are not the same as those in the Supreme Court case, which was a separate matter." *See arstechnica.com*, August 7, 2013.

French Court Upholds Law Easing Restrictions on Stem-Cell Research

The French Constitutional Council has determined that a stem-cell research law approved by the National Assembly in July 2013 is constitutional, thus rejecting an effort launched by conservatives, who introduced some 300 amendments during debate, to invalidate it. The new law will reportedly make it easier to conduct research on human embryos and stem cells, bypassing approval from the national biomedicine agency, but will still require compliance with each of four criteria: the research has scientific relevance, it is performed for medical purposes, it cannot be done without resort to the use of embryos and embryonic stem cells, and it otherwise respects ethical principles. *See Science Insider*, July 17, 2013; *Reuters*, August 1, 2013.

NEWS BYTES

The U.S. Food and Drug Administration (FDA) **requests** comments on draft guidance titled "Minimizing Risk for Children's Toy Laser Products." According to FDA, the document is intended to "inform manufacturers of laser products, FDA headquarters and field personnel, and the public of the Center for Devices and Radiological Health's (CDRH) proposed approach on the safety of toy laser products." Comments are requested by November 5, 2013.

The U.S. Food and Drug Administration **schedules** a September 9-10, 2013, Pediatric Ethics Subcommittee meeting, in Silver Springs, Maryland. The subcommittee advises and makes recommendations to FDA's Pediatric Advisory Committee and will discuss "ethical issues in pediatric product development, including medical counter measures, focusing on the concepts of minimal risk, disorder or condition, and exposure of pediatric

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subjects to risks under 21 CFR 50.54." Those wishing to speak must provide notice of their intent to do so by August 30, and written comments are requested by September 9.

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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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