Shook, Hardy & Bacon L.L.P.

ISSUE 50 | FEBRUARY 8, 2013

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Commenters Weigh-In on USPTO's "True Owner" Disclosure Proposal

Among those commenting on a U.S. Patent and Trademark Office (USPTO) proposal to collect and disseminate information about the real-party-in-interest (RPI) for patent applications and issued patents, was the Intellectual Property Owners Association (IPO), which expressed concerns in a January 29, 2013, **letter** about RPI identification and burdens that a broad RPI definition would have on rights holders. Additional information about USPTO's proposal appears in Issue **47** of this *Bulletin*.

Among other matters, the trade organization contends that "a broadly defined RPI would require researching corporate law and frequently changing corporate structures; examining complex IP transactions with numerous parties, including co-owners and licensees who may or may not hold all substantial rights; and analyzing and resolving conflicts between US and foreign law." IPO also suggests that USPTO's stated justifications for requiring this information may be flawed and recommends that USPTO "investigate further whether it has authority to require patent ownership information." According to IPO, a general statutory duty requiring USPTO to disseminate "to the public information with respect to patents" may simply "refer to relaying information on hand, not collecting or requiring new information." IPO also observes, "Congress appears to have determined that providing patent assignment information to the USPTO is optional."

Other commenters have reportedly lined up in favor of the proposal, including the American Antitrust Institute, which opined that improvements to the patent ownership record "can help operating companies, both incumbents and potential new entrants, manage their legal risk and reduce their search costs." *See The National Law Journal*, January 30, 2013.

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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 Life Sciences and Biotechnology capabilities, please contact

John Garretson
Intellectual Property
816-559-2539
jgarretson@shb.com

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

Chris Johnson
Life Sciences & Biotechnology
415-544-1900
cjohnson@shb.com

Madeleine McDonough
Pharmaceutical & 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.

INVESTOR NEWS

Trius Raises $34.1 Million to Advance Antibiotics Development

San Diego-based biopharmaceutical company Trius Therapeutics, Inc. has announced that the underwriters of its previously announced public offering of common stock that priced on January 17, 2013, have exercised their option to purchase an additional 869,135 shares of common stock. Trius reports that with the sale of the additional shares, it will have sold 7.16 million shares of common stock at $4.75 per share. Gross proceeds to the company are reported to be about $34.1 million, and the offering was expected to close January 24. Trius evidently plans to use proceeds from the offering for "general corporate purposes, including clinical trial, preclinical and other research and development expenses, capital expenditures, working capital and general and administrative expenses."

Trius manufactures antibiotics for serious infections, including tedizolid phosphate, a second generation oxazolidinone currently in Phase 3 clinical development to treat serious gram-positive infections. Among the company's infection targets are those caused by methicillin-resistant *Staphylococcus aureus*, otherwise known as MRSA. *See Trius Therapeutics, Inc. Press Release*, January 23, 2013.

Antibody Drug Developer Announces IPO

A biopharmaceutical company headquartered in San Francisco has reportedly sold 8.75 million shares at $8 after its initial public offering (IPO) in a deal valued at approximately $70 million. According to a news source, KaloBios Pharmaceuticals Inc. will use the funds to develop and advance its "Humaneered" technology, which converts non-human antibodies—usually from mice—into human antibodies. The engineered antibodies apparently bind more easily to their targets, which the company believes makes those drugs more effective against disease with fewer side effects.

The company reportedly began a 180-patient, Phase 2 study of its lead drug, KB-001-A in cystic fibrosis patients in January and has an ongoing Phase 2 study of KB-003 in severe asthma patients. KaloBios granted underwriters a 30-day option to buy more than 1.3 million additional shares. *See KaloBios Pharmaceuticals Inc. Press Release* and *The Wall Street Journal*, January 31, 2013.

Phase 2 Study for Acceleron's Anemia Treatment to Begin

Biopharmaceutical company Acceleron Pharma, Inc. has announced the initiation of a phase 2 study of its investigational protein therapeutic, ACE-536, to treat anemia in patients with myelodysplastic syndromes (MDS)—malignancies of the bone marrow that can reportedly cause severe and chronic anemia. The Cambridge, Massachusetts-based developer of protein therapeutics for

cancer and orphan diseases also announced that it has earned a $10-million milestone payment for initiating the study. Acceleron is reportedly developing ACE-536 in collaboration with New Jersey-based Celgene Corp.

"ACE-536 has the potential to make a significant impact on the treatment of anemia in MDS," said Acceleron CEO Matthew Sherman. "Unlike erythropoietin, ACE-536 may target the specific defect in the erythropoietic maturation process in MDS patients, and we are optimistic that it could become an important new therapeutic option for this underserved patient population." *See Acceleron Pharma, Inc. Press Release*, January 29, 2013.

ArQule Starts Late-Stage Liver Cancer Trial

Massachusetts-based cancer drug developer ArQule, Inc. has reportedly announced that the first patient has been enrolled in a Phase 3 trial of tivantinib against liver cancer. The study will assess tivantinib's efficacy in previously treated liver cancer patients who are not candidates for surgery and who have high levels of the receptor tyrosine kinase known as MET, which is evidently believed to increase cancer cell growth, invasion and metastasis. ArQule CEO Paolo Pucci said in this regard, "Hepatocellular carcinoma [HCC] is a devastating disease, and patients with advanced HCC are in need of new therapies that can help extend their lives. The METIV-HCC trial follows positive Phase 2 results that demonstrated improvements in overall survival and time to progression observed among MET-high patients."

Meanwhile, ArQule's Japanese development partner, Daiichi Sankyo, has reportedly paid ArQule a $15-million milestone fee for initiating patient enrollment in the tivantinib study.

"We are very pleased to begin this Phase 3 trial to advance our understanding of the potential role of tivantinib in the treatment of HCC," said Glenn Gormley, Daiichi Sankyo's global head of research and development and senior executive officer. "It is our hope that this late-stage study will confirm the positive results we saw in Phase 2 in time to progression (TTP) and overall survival (OS) observed in patients whose tumors were MET-high." *See ArQule Press Release*, January 31, 2013; and *Boston Business Journal*, February 1, 2013.

BUSINESS CLIMATE

Life Sciences Investment Manager Releases 2012 Pharma/Biotech M&A Report

HBM Partners has issued a **report** on 2012 mergers and acquisitions (M&A) in the pharmaceutical and biotechnology sectors in North America and Europe, noting that while M&A activity is strong in the United States, it is weaker in Europe. Deal volumes were reportedly lower in 2012 than in 2010 and 2011, but "[i]f one excludes transactions over $10 billion (1 in 2012, 2 in 2011 and 1

in 2010), then 2012 looks quite strong with $32.3 billion of transaction volume (vs. less than $30 billion in 2011 and in 2010)." The number of transactions in 2012 was comparable to prior years, and dominant buyers were apparently North American large pharmaceutical and biotechnology firms and specialty pharmaceutical companies.

Overall returns to venture capital (VC) investors have reportedly increased in both the United States and Europe since 2009, but "US deals have generated substantially better returns during the last 4 years." The report also notes that the time from startup to trade sale "has significantly increased since 2005. Whereas the average 'time to exit' was a bit more than 5 years in 2005 it has now increased to almost 9 years, indicating that VC-backed companies have to develop their products in later-stage clinical trials before they can orchestrate a trade sale." HBM Partners is a health care-focused investing company with some $800 million under management.

Life Sciences Grow in Kansas City Region

According to data released by the Kansas City Area Life Sciences Institute, Inc., the number of life sciences companies in the region has grown 17 percent since 2009 with an accompanying 21-percent increase in employment in this sector. Most of the 240 life sciences companies within the 24-county area responding to a survey about hiring trends indicated that they planned to add employees during the next 36 months. The institute also reported that the largest cluster of animal health company employers is based in and around St. Joseph, Missouri, and that 13 percent of the life sciences companies are located in Columbia, Missouri. Small medical device companies have reportedly had the largest relative increase among industry subsectors, growing 28 percent since 2009.

The institute's director of program development said, "National statistics indicated that the biotechnology sector weathered the Great Recession very well. It's great to see that trend validated in our region." CEO Wayne Carter was quoted as saying, "we had really remarkable growth in Kansas City in the life sciences sector. That's a really big story." *See Kansas City Area Life Sciences Institute, Inc. News Release* and *Kansas City Business Journal*, January 31, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Bipartisan Bill Introduced to End "Pay-for-Delay" Agreements

U.S. Sens. Amy Klobuchar (D-Minn.) and Chuck Grassley (R-Iowa) have introduced a bill (S. 214) that would prohibit the manufacturers of brand-name drugs from entering agreements with generic drug makers to delay the entry of a generic drug into the market. According to Klobuchar, "These pay-for-delay deals keep more affordable generic drugs off the market, hurting

consumers and stifling competition." The "Preserve Access to Affordable Generics Act" would stop this practice. Grassley called the deals "anti-competitive patent settlements between brand and generic drug companies [that] hurt consumers' access to affordable medications." The proposed legislation was referred to the Senate Judiciary Committee. *See Sen. Amy Klobuchar Press Statement*, February 5, 2013.

Could a National GMO Foods Labeling Program Become a Reality?

According to a January 31, 2013, *New York Times* article, executives from a number of major food and beverage companies, including General Mills, PepsiCo and grocery retailers, as well as certain pro-labeling advocacy groups, attended a Food and Drug Administration meeting in Washington, D.C., in January to discuss a mandatory federal genetically modified organism (GMO) labeling law.

According to the article, rather than quelling the demand for labeling, the recent defeat of California's Proposition 37 has "spawned a ballot initiative in Washington State and legislative proposals in Connecticut, Vermont, New Mexico and Missouri, and a swelling consumer boycott of some organic or 'natural' brands owned by major food companies." In fact, news sources indicate that a proposal to require labeling of GMO food in Washington—**Initiative 522**—has apparently gathered enough support to clear the signature check process and potentially make it to the state's November ballot for a public vote; some 20 other states are evidently making headway on their initiatives to mandate labeling.

"The big food companies found themselves in an uncomfortable position after Prop. 37, and they're talking among themselves about alternatives to merely replaying that fight over and over again. They spent a lot of money, got a lot of bad press that propelled the issue into the national debate and alienated some of their customer base, as well as rais[ed] issues with some trading partners," Washington State University Research Professor Charles Benbrook told *The New York Times*. Additional information about GMO labeling can be found in Issues **466** and **461** of Shook, Hardy & Bacon's *Food & Beverage Litigation Update*. *See The New York Times*, January 31, 2013; *nationofchange.org* and *The Seattle Times*, February 4, 2013.

EU Medical Device Manufacturers Address Plan to Change Regulatory Directives

Eucomed, an organization that represents the interests of the European medical device industry, has issued a position **paper** that assesses a number of changes the European Commission (EC) has proposed making to European Union (EU) medical device directives. While Eucomed supports most of the recommended changes, it also objects to those which are either insufficiently stringent or would lead to delays in the approval of new medical devices. Among other matters, Eucomed calls for a "systematic control procedure" to

regulate "Notified Bodies," which certify the safety and efficacy of medical devices, rather than the EC's proposed "scrutiny procedure" that would, among other things, introduce random sampling of certain class III medical devices after Notified Bodies have completed their reviews. Eucomed is also concerned about a proposed publicly accessible database on medical device safety and quality, observing that it "lacks clarity on how exactly this information will be made available to various stakeholders and also lacks detail regarding the system's structure, funding and resource allocation."

New Medical Device Regulations Issued in Malaysia, Effective July 1

Malaysia's Minister of Health has approved medical device **regulations** under the Medical Device Act 2012 (Act 737); they were published in the *Federal Government Gazette* at the end of 2012. According to a Ministry of Health news release, the regulations, in part, "specify requirements and procedural matters pertaining to medical device registration, conformity assessment body (CAB) registration, establishment licensing, export permit and appeal." While the regulations will take effect July 1, 2013, "a transition period of two years for medical device registration and one year for establishment licensing will be given to the industry before it is fully enforced."

LITIGATION

Amici Add Briefs on "Pay-for-Delay" Issue to SCOTUS Docket

As oral argument nears in a case before the U.S. Supreme Court addressing whether payments made to generic drug makers who agree to delay entry into the market for a period of time in abrogation of their rights under the Hatch-Waxman Act and its amendments, a number of *amici* have filed briefs supporting the Federal Trade Commission's position that such agreements are presumptively anti-competitive. *FTC v. Watson Pharms., Inc.*, No. 12-416 (U.S., oral argument scheduled for March 25, 2013).

U.S. Rep. Henry Waxman (D-Calif.) argues in his **brief** that "judicial decisions shielding reverse-payment agreements between brand-name and generic drug manufacturers from stringent antitrust scrutiny stand as a significant obstacle to the fulfillment of the important public policies embodied in the Hatch-Waxman Amendments and their 2003 revisions." He cites the significant savings to government and consumers if generic drug makers are not authorized "to exact a share of a brand-name drug owners' monopoly profits in return for *staying out of the market*."

Arguing on behalf of 36 states, the District of Columbia and Puerto Rico, New York Attorney General Eric Schneiderman also urges the Court to "adopt a presumption that pay-for-delay drug patent settlements are anticompetitive and unlawful." In their **brief**, the attorneys general contend that they "have

strong interests, both as pharmaceutical purchasers and as antitrust enforcers, in protecting fair competition in pharmaceutical markets." In their view, "when a settlement agreement specifying an agreed entry date also includes a payment from the brand-name manufacturer to the potential generic competitor, that payment ordinarily represents an unlawful inducement to the generic to agree to delay entry into the market for a longer period than is warranted by the parties' evaluation of the patent's merits."

A joint **brief**, filed on behalf of AARP, the American Medical Association, National Legislative Association for Prescription Drug Prices, and U.S. Public Interest Research Groups, claims that patients will skip doses of prescribed medicines due to their high cost, stating "Brand-name firms have used exclusion agreements to delay entry of generics by an average of seventeen months and to terminate patent challenges that would otherwise generate *billions* of dollars in consumer savings." They claim that "the lack of low cost treatment options reverberates throughout the entire health care system," especially when patients forego expensive prescriptions and require a higher cost of care over time as their untreated conditions worsen.

Some commentators have suggested that the U.S. Supreme Court will likely uphold the Eleventh Circuit and that it will be up to Congress to make the changes needed to fix the Hatch-Waxman Act flaws that have led to what *amici* consider to be less than optimal unforeseen consequences. *See Politico*, January 30, 2013.

NEWS BYTES

The Food and Drug Administration issues **guidance** titled "Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling." The guidance is intended to help "the pharmaceutical industry and other investigators engaged in new drug development in evaluating how variations in the human genome, specifically DNA sequence variants, could affect a drug's pharmacokinetics (PK), pharmacodynamics (PD), efficacy, or safety." Comments may be submitted at any time.

The Food and Drug Administration (FDA) issues **guidance** titled "Guidance for Industry and Food and Drug Administration Staff: Humanitarian Use Device (HUD) Designations." Designed to help applicants prepare and submit HUD designation requests and FDA reviewers evaluate these requests, the guidance includes information about demonstrating that a "device is designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year" and how such demonstrations may vary "depending on whether the device is intended for therapeutic or diagnostic purposes."

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The Food and Drug Administration's (FDA's) Science Board **schedules** a meeting for February 27, 2013, in Silver Spring, Maryland, to consider reports and updates relating to the recently established Center for Biologics Evaluation and Review Post-Marketing Safety Review subcommittee, as well as genomics activities at the Centers for Food Safety and Applied Nutrition and Veterinary Medicine. Those wishing to speak during the meeting must notify FDA by February 13, and written submissions are requested by February 20.

The U.S. Patent and Trademark Office **seeks** "stakeholder input on certain matters relating to international harmonization of substantive patent law, in particular, information and views on: (1) The grace period; (2) publication of applications; (3) the treatment of conflicting applications and (4) prior user rights." It will conduct a public hearing on March 21, 2013, in Alexandria, Virginia. Those wishing to present oral testimony must submit a request by February 28; written comments and answers to an electronic questionnaire, developed by patent office representatives from Denmark, France, Germany, Japan, the United Kingdom, United States, and European Union "to aid in the acquisition and analysis of stakeholder views across jurisdictions," are also requested by February 28.

The U.S. Patent and Trademark Office **requests** comments on information collection burdens, in terms of estimated response time and expense, associated with patent applications submitted under the Patent Cooperation Treaty, which provides "a standardized filing format and procedure that allows an applicant to seek protection for an invention in several countries by filing one application in one location, in one language, and paying one initial set of fees." Comments are requested by April 5, 2013.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400

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