Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Science Publisher Claims Submission of Prior Art to USPTO Involves Copyright Infringement

A New Jersey-based publishing company has filed copyright infringement lawsuits in federal courts in two states against law firms that submitted citations to or copies of copyrighted articles from scientific journals to the U.S. Patent and Trademark Office (USPTO) with their clients' patent applications. *John Wiley & Sons, Ltd. v. McDonnell Boehnen Hulbert & Berghoff LLP*, No. 12-01446 (U.S. Dist. Ct., N.D. Ill., filed February 29, 2012); *Am. Inst. of Physics v. Schwegman, Lundberg & Woessner*, No. 12-00528 (U.S. Dist. Ct., D. Minn., filed February 29, 2012). Joining the publisher as plaintiff is the American Institute of Physics.

The litigation follows release of the January 19, 2012, position paper from USPTO's Office of the General Counsel opining that (i) the inclusion of copies of patented scientific articles in the official file wrapper as part of the patent examination process constitutes fair or transformative use, and (ii) applicants submitting these articles with their applications are also protected under these doctrines. Further details about the position paper appear in Issue 28 of this *Bulletin*. The USPTO general counsel's paper did not take a position on whether additional copies made "during the course of patent prosecution (e.g. for the client, for other attorneys, for the inventor, or for the law firm's future reference) qualify as fair use."

The plaintiffs contend that "in connection with researching, filing and prosecuting certain patent applications," the law firms made unauthorized copies of copyrighted articles from the plaintiffs' journals. The infringing copies allegedly include "additional copies of the copyrighted works that defendants included or cited in their patent application to the [USPTO] . . . and copies of plaintiffs' copyrighted works that defendants considered in connection with those applications, but did not ultimately cite or provide to the [USPTO]." According to the complaint, the unauthorized "multiplication of copies" was made for internal use and for distribution outside the firms.

Alleging a single count of copyright infringement, the plaintiffs seek injunctive relief, "damages or defendants' profits, or alternatively, at plaintiffs'

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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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If you have questions about this issue of the Report, or would like to receive supporting documentation, please

election, statutory damages," costs, and attorney's fees. Each complaint cites two specific articles from three journals that were allegedly infringed.

NEW BIO BUSINESS VENTURES

Companies Partner to Develop Soybean Venture

Arcadia Biosciences Inc., an agricultural technology company based in Davis, California, and Bioceres, an Argentina-based agricultural investment and development company owned by hundreds of the largest South American soybean growers, have formed a 50-50 joint venture known as Verdeca. The joint venture will "develop and deregulate soybean varieties with next generation agricultural technologies," according to the companies.

"Verdeca's initial focus will be on drought tolerance technology developed by Bioceres and demonstrated through multiple seasons of field trials, and on nutrient efficiency technology developed by Arcadia, which increases crop yield," the companies said. Bioceres and Arcadia have already invested $120 million in the joint venture's technologies, with Verdeca planning to invest up to $30 million in further development. "Arcadia's global regulatory expertise and validated technologies are of great value to Bioceres and are key assets to this initiative," said Bioceres CEO Federico Trucco. *See Arcadia Biosciences Press Release*, February 28, 2012.

INVESTOR NEWS

Taiwan, New Zealand Enter Green, Biotech Venture Capital Deal

Taiwan and New Zealand have reportedly signed an investment agreement establishing a joint venture capital fund to benefit the green and biotech sectors in their countries. Apparently making Taiwan the first country to enter such a deal with New Zealand, the agreement requires each country to contribute half of the US$169.5-million investment fund. Applications from start-up companies will be accepted in the fourth quarter of 2012, with each country investing 30 percent in qualified start-ups and the remaining 40 percent funded by the private sector.

"For companies in New Zealand, Taiwan has potential to become a second base of operations rather than just a springboard to the China market," Taiwan's National Development Fund Executive Secretary Lin Huan was quoted as saying. "This means they are likely to set up operations here." *See The China Post*, March 6, 2012.

Russian Nanotech Investment Fund Joins U.S. Venture Capital Firm

RUSNANO, founded through the reorganization of the Russian Corporation of Nanotechnologies, and Domain Associates, a U.S. venture capital firm specializing in life sciences technologies, have announced a joint venture that will invest approximately $760 million in U.S. pharmaceutical, diagnostics and medical device companies and create a life-sciences manufacturing plant in Russia while increasing drug development there.

The companies said the funding will primarily target some 20 companies involved with developing advanced drugs for a variety of medical conditions "that have significant applications for patient populations in Russia," such as viral infections, cardiovascular diseases and cancer. The Russian pharmaceutical and medical device manufacturing facility will meet good manufacturing practice standards, the companies noted, adding that the joint venture will leverage the innovations created by their investment portfolio companies and obtain exclusive rights to manufacture and market products in Commonwealth of Independent States countries, including the Ukraine, Belarus and Kazakhstan. The companies have engaged the management company Team Drive to develop the project.

"We expect Domain's collaboration with RUSNANO to provide a significant boost to the modernization efforts of the Russian pharmaceutical and medical technology industry," said Domain Partner Brian Dovey. "For our portfolio companies, this strategic relationship opens up new attractive avenues for financing. Finally, we are excited about the commercial potential of establishing a cutting-edge production facility in Russia." *See RUSNANO, Domain Associates* and *Team Drive Press Release*, March 6, 2012.

Biotech Spun from Children's Hospital of Philadelphia Raises $7 Million for Nanotech Drug

Vascular Magnetics, the first start-up company founded on research developed at The Children's Hospital of Philadelphia, has reportedly raised $7 million to "advance development of an innovative drug delivery system using magnetically targeted nanoparticles to treat peripheral artery disease." Based in West Philadelphia, Vascular Magnetics uses a system that "guides the particles to the walls of arteries" narrowed by disease. The particles remain in place at the disease site, slowly biodegrading and releasing a drug called paclitaxel, which prevents the artery's re-obstruction.

"It's exciting to see that one of our hospital's research discoveries has attracted investors to move it toward commercial development," said Philip Johnson, the hospital's chief scientific officer and executive vice president. "This work can have multiple benefits—directly to patients receiving a new treatment, and also to children whose lives will be improved by future research supported by revenue generated by this technology." *See The Children's Hospital of Philadelphia News Release,* February 27, 2012.

Boston Biotech Secures $20 Million to Develop Antibody Technology

4s3 Bioscience, Inc., a Boston-area biotechnology company, has reportedly closed a $20-million Series A financing round with KLP Enterprises LLC, to support "continued development of a proprietary antibody technology that provides targeted and active intracellular delivery of active proteins, enzymes and other macromolecules to skeletal muscle." Financial details of the deal were not disclosed.

The company claims that its technology enables the replacement of deficient proteins to skeletal muscle "and holds promise for treating the underlying causes of muscular dystrophies, myopathies, motor neuron diseases, diseases of the neuromuscular junction, and various enzyme deficiency disorders." According to 4s3 Vice-President of Research Dustin Armstrong, "A major obstacle to the treatment of genetic neuromuscular diseases is the challenge of delivering functional macromolecules to skeletal muscle tissue. Our approach represents a novel therapeutic strategy to address numerous indications with no currently approved therapies." *See 4s3 Press Release*, March 5, 2012.

San Diego-Based Bioenergy Crop Co. Secures $17 Million for Hybrid Seeds

SG Biofuels, Inc., (SGB), a San Diego-based bioenergy crop company developing hybrid seeds that grow a low-cost feedstock for biodiesel, bio jet fuel and specialty chemicals, has reportedly completed a $17-million Series B financing. Led by health care venture firm Thomas, McNerney & Partners, the funding also included participation from new investor Finistere Ventures and current investors Flint Hills Resources, LLC and Life Technologies Corp.

Noting that it will use the funding to expand research and development, advance marketing efforts and scale global operations, SGB said it is developing elite hybrid seeds of Jatropha, a subtropical, non-edible energy crop grown on marginal lands considered undesirable for food crops. "SGB has signed customers for the deployment of 250,000 acres of Jatropha using its JMAX™ hybrid seeds," the company said, including an agreement with Brazil's JETBIO, which plans to deploy 75,000 acres for the production of bio jet fuel. *See SG Biofuels Press Release*, January 17, 2012.

BUSINESS CLIMATE

Rebecca Hersher, "Small biotechs raring to cash in on the orphan disease market," *Nature Medicine*, March 2012

This news item identifies several small biotechnology companies that have focused their research and development activities and acquisition strategies on drugs that can cost patients in excess of $200,000 a year to treat

rare diseases. Following the business model pioneered by another biotech that commanded a high acquisition price when it was sold in 2011, these companies, located in Switzerland, California and the northeast United States, are testing drugs that each may treat fewer than 10,000 afflicted individuals worldwide. Some companies, such as Cambridge, Massachusetts-based Aegerion Pharmaceuticals, are developing a single compound and minimizing overhead costs by hiring physicians to identify patients rather than hiring hundreds of sales representatives. A senior market analyst in New York was quoted as saying, "With orphan drugs like this one [Aegerion's lomitapide] where there is clearly an unmet need, the likelihood of approval is high." He apparently expects lomitapide, used to treat people with blood cholesterol levels so high they frequently have strokes and heart attacks as teenagers, to be approved in early 2013. An estimated 7,000 are thought to have the disease.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Senate Approves Bill to Crack Down on Counterfeit Drugs

The U.S. Senate has unanimously passed a bill (S. 1886) that would increase penalties for trafficking counterfeit drugs "to reflect the severity of the crime and the harm to the public." The Counterfeit Drug Penalty Enhancement Act would target violators "that knowingly manufacture, sell or traffic counterfeit medicines to the United States," according to Senators Chuck Grassley (R-Iowa) and Patrick Leahy (D-Vt.), who co-authored the bill.

Noting that under current law counterfeit drug traffickers face the same fines as those trafficking any other counterfeit product, the senators said that they introduced the measure in response to the administration's Counterfeit Pharmaceutical Inter-Agency Work Group's recommendation to increase counterfeit-drug penalties. Under the bill, a person convicted of counterfeit drug trafficking could face up to $4 million in fines for a single offense and $8 million for multiple offenses, and up to 20 years in prison.

"Worldwide, counterfeit medicines are a multi-billion dollar industry and growing at an alarming pace, especially over the Internet," Grassley said. "These medicines pose a serious threat to the health and safety of unsuspecting Americans. The House should act as quickly as possible to ensure that counterfeit drug traffickers are punished accordingly for putting people's lives at risk with this serious crime." *See Press Releases of Senators Chuck Grassley and Patrick Leahy*, March 7, 2012.

FDA Schedules Public Hearing on Biosimilar Guidance Documents

The Food and Drug Administration (FDA) has **scheduled** a May 11, 2012, public hearing in Silver Spring, Maryland, "to obtain input on recently issued draft guidances relating to the development of biosimilar products." Information about and links to the draft guidances appear in **Issue 29** of this *Bulletin*. FDA is also soliciting input on topics for future biosimilars-related policies.

Those wishing to present during the public hearing must register by April 11, and FDA will accept written comments until May 1. A live Webcast can be viewed at **http://www.fda.gov/Drugs/NewsEvents/ucm265628.htm** on the day of the hearing, and a recording will be available at the same site for one year.

According to its *Federal Register* notice, FDA is requesting comments "from a broad group of stakeholders, such as health care professionals, health care institutions, manufacturers of biomedical products, interested industry and professional associations, patients and patient associations, third party payers, current and prospective BLA [biologics license application] and new drug application (NDA) holders, and the public." Specifically, FDA seeks feedback on whether (i) particular issues in the guidance documents have been addressed satisfactorily, (ii) the agency should have addressed other issues, (iii) FDA's thinking "is sufficiently clear to provide meaningful guidance to stakeholders," and (iv) the usefulness and clarity of the documents can be enhanced. *See Federal Register*, March 2, 2012.

Meanwhile, a *Nature Biotechnology* editorial contends that FDA's pathway to approval for biosimilars may make it difficult for all but brand manufacturers to demonstrate that a biosimilar product is clinically similar to the reference product. According to the editorial, FDA went further than what is already required in the European Union and appears to be calling for identity with the reference product rather than with defining similarity. It also states that biologics originators "will find in the guidances a pleasingly detailed and potentially arduous path for any biosimilar manufacturer hoping to cut into a market share of their brand products. Such US brand companies may also see the clarifications about FDA's biosimilar pathway as a basis for going out and buying companies that already have a foothold in the European biosimilars space, whether European, Indian, Chinese, Korean or otherwise. Because the FDA is placing so much emphasis on analytical characterization and proof of similarity, brand manufacturers will be in a strong position to use their internal confidential business information about biomanufacturing processes in biosimilar subsidiaries to create new revenue streams." *See Nature Biotechnology*, March 2012.

FDA Seeks Input on Modernizing Regulation of Clinical Trials

The Food and Drug Administration (FDA) will hold a two-day public hearing "to solicit public input from a broad group of stakeholders on the scope and direction" of its effort "to modernize the regulatory framework that governs clinical trials and approaches to good clinical practice." Scheduled for April 23-24, 2012, in Silver Spring, Maryland, the hearing will also provide a forum for ideas about using "innovative models that may enhance the effectiveness and efficiency of the clinical trial enterprise." Those wishing to participate must register by April 2, and electronic or written comments may be submitted until May 31. A live Webcast during the hearing can be viewed at http://www.fda.gov/Drugs/NewsEvents/ucm284118.htm, and a recording will be available at the same site for one year.

Noting that regulations governing the conduct of clinical trials and the protection of human subjects were created more than 25 years ago and that dramatic changes have occurred in clinical trials in the intervening years, FDA outlines steps it has already taken to change its oversight approach. With a primary focus on "good clinical practice" (GCP) to ensure trial quality, data integrity and human subject protection, FDA "is seeking feedback on specific GCP regulations, policies, and practices that may need clarification or revision to facilitate advances in the ways that clinical trials are conducted, remove impediments to the use of innovative approaches, or otherwise improve the conduct of clinical trials."

Among the specific questions FDA has posed are those relating to the challenges posed by increased clinical trial complexity and globalization, particular models or technological advances that could safely and effectively streamline the conduct of clinical trials, regulatory impediments to clinical trial practice, and agency oversight priorities. *See Federal Register*, March 7, 2012.

FDA Issues Guidance on Acceptance of Foreign Clinical Studies Not Conducted Under IND

The Food and Drug Administration (FDA) has issued guidance titled "Guidance for Industry and FDA Staff: FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND, Frequently Asked Questions." This document is intended to assist those seeking to demonstrate compliance with 21 C.F.R. 312.120, which requires that foreign clinical studies not conducted under an investigational new drug application (IND) but submitted as support for an IND or an application for marketing approval "be conducted in accordance with good clinical practice (GCP), including review and approval by an independent ethics committee (IEC) and informed consent from subjects." The agency issued the guidance "as part of its efforts to encourage sponsors and applicants to standardize information relating to foreign clinical trials in the

INDs and applications for marketing approval" and "to strengthen oversight of foreign clinical trials."

France Publishes Decree Requiring Nanomaterial Reporting in 2013

The French Ministry for Ecology, Sustainable Development, Transportation and Housing has reportedly published a final decree requiring manufacturers, importers and distributors of nanomaterials, in addition to research laboratories and "professional users," to submit to authorities an annual declaration about the quantities and use of nanoparticle substances or nanomaterials placed on the French market. Applicable in 2013, the decree represents the first mandatory reporting scheme for nanomaterials in Europe.

It requires quantities of 100 g or more to be reported and defines a substance with nanoparticle status as a substance "intentionally manufactureed to a nanometric scale and containing particles in an unbound state or as an aggregate or as an agglomaerate and where, for a minimum proportion threshold of the particles in number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. Where warranted, however, "by concerns for the environment, health, safety or competitiveness, the minimum proportion of number size distribution threshold can be reduced." *See Safenano.org,* March 9, 2012.

LITIGATION

Drug Companies and Policymakers Watch Patent Dispute Before India's High Court

According to a news source, the India Supreme Court will hear final arguments in March 2012 on whether the manufacturer of a drug that could not be patented in India because it was created before 1995 during a moratorium on the grant of patents to Western companies, may obtain a patent in that country for a newer form of the drug. At issue is the treatment for a deadly form of leukemia. Under Indian law, a newer form of a known substance cannot be patented unless it significantly improves the drug's efficacy. Drug maker Novartis contends that the current version of its cancer drug is 30 percent easier for the body to absorb than the chemical it patented in the early 1990s in the United States and other countries but never marketed as a drug. The company has reportedly resisted pressure to drop the case, hoping that the Court will define what product attributes constitute increased efficacy.

The case has apparently pitted the makers of branded drug products against those manufacturing generics and implicates policy issues among trading partners. The Obama administration objects to India's protective patent provision and is seeking an agreement from nations negotiating the Trans-Pacific Partnership, a new Pacific Rim trade pact, to grant patents under circum-

stances similar to those in the case currently before India's high court. Doctors Without Borders and other public health interests advocate generic drugs and oppose Novartis's efforts to gain protection for expensive branded medicines; the drug at issue can cost as much as $70,000 a year in the United States. The Indian government has denied patents for many drugs made by Western companies, which has apparently allowed its generics industry, exporting about $10 billion annually in generic medicines primarily to developing countries, to prosper. *See The New York Times*, March 7, 2012.

Federal Court Transfers Patent Owners' Reexamination Challenge to Federal Circuit

A federal court in the District of Columbia, addressing a statutory construction matter of first impression, has determined that the 1999 amendments to U.S. patent law do not allow a patent owner to file a civil suit in federal court challenging an adverse *ex parte* reexamination decision of the U.S. Patent and Trademark Office's Board of Patent Appeals and Interferences (BPAI). *Teles AG v. Kappos*, No. 11-00476 (U.S. Dist. Ct., D.D.C., decided March 5, 2012). Rather, patent owners are required, according to the court, to appeal such BPAI determinations to the Federal Circuit Court of Appeals, thus limiting review to the BPAI record.

So ruling, the court exhaustively examines Congress's creation of and modifications to the Patent Act reexamination process since 1980, including legislative proposals, and concludes that the "1999 amendments were reforms grounded in Congress'[s] ongoing efforts to streamline and improve the reexamination system in the Patent and Trademark Office in order to make it a 'more viable' alternative to litigation." The court further notes that the patent reforms enacted in 2011 "clarify any ambiguity left by the 1999 amendments, and confirm for the Court that Congress intended the 1999 amendments to remove this Court's jurisdiction over patent owners' *ex parte* reexamination claims." While patent owners have just one avenue for BPAI review under the court's interpretation, patent applicants retain the right to either appeal directly to the Federal Circuit Court of Appeals or to bring a civil action in the District of Columbia district court where they are not limited to the BPAI record "but may undertake discovery and introduce new evidence."

NEWS BYTES

The Food and Drug Administration publishes its annual **report** on the status of the postmarketing studies or clinical trials that drug and biologics firms holding approved drug and biological products are either required or have committed to conduct.

The National Nanotechnology Coordination Office **announces** a "2012 Regional, State and Local Initiatives in Nanotechnology Workshop" on May 1-2 in Portland, Oregon, to bring together representatives of industry, busi-

ness, government, and academia to address resource, organizational and policy issues affecting regional, state and local nanotechnology initiatives. Comments are requested by April 27.

The Animal and Plant Health Inspection Service (APHIS) announces that it is "implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for genetically engineered organisms to allow for early public involvement." The agency will publish two *Federal Register* notices for public comment under the new procedure: first, to announce the availability of the petition and second, to announce the availability of APHIS's decision-making documents.

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Practice Partners Scott Sayler and David Brooks will participate in DRI's Drug and Medical Device Seminar slated for May 10-11, 2012, in New Orleans, Louisiana. Co-sponsored by SHB, the event will feature "trial skills demonstrations, panel discussions of judges overseeing coordinated pharmaceutical proceedings, and litigation insights from leading defenders of drug and device cases." Brooks will present a session titled "When a Good Medical Device Fails: Successfully Defending Medical Device Suits When Causation Is Not in Doubt," which will address the substantive and strategic consideration of defending these cases. Sayler will also deliver remarks as chair of DRI's Drug and Medical Device Committee.

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