Shook, Hardy & Bacon L.L.P.

ISSUE 34 | MAY 3, 2012

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

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IP NEWS

Law Firm Targeted by Science Publisher Answers Copyright Infringement Complaint

The law firm that was sued for copying and disseminating copyrighted articles from scientific journals for submission with its clients' patent applications to the U.S. Patent and Trademark Office (USPTO) has filed its response to the copyright infringement claims. *John Wiley & Sons, Ltd. v. McDonnell Boehnen Hulbert & Berghoff LLP*, No. 12-CV-01446 (U.S. Dist. Ct., N.D. Ill., E. Div., pleading filed April 19, 2012). Additional information about the lawsuit appears in Issue 31 of this *Bulletin.* Among other matters, the response notes that USPTO's position paper characterizes copying and submitting non-patent literature to satisfy the office's disclosure requirements as "fair use." It also contends that an adverse judgment would "interfere with the federal government's interest in promoting an inexpensive and efficient patent system whereby prior art is appropriately disclosed."

Specifically, the law firm "denies that it has made or distributed unauthorized copies of copyrighted articles from plaintiffs' journals," while admitting to the disclosure of non-patent literature to USPTO "as part of its legal obligation to file an Information Disclosure Statement with the Patent Office in conjunction with filing and prosecuting a patent application." The firm denies outright making (i) additional copies of copyrighted works that were either cited in patent applications or ultimately not cited, or (ii) unauthorized copies for internal use or distribution outside the firm. The complaint also alleged that the firm "charged its clients for the copies it has made of plaintiffs' copyrighted works, and thereby made a direct profit as a result of its infringement," and the firm denies this allegation as well.

Among the firm's affirmative defenses are fair use; immunity from liability under the *Noerr-Pennington* doctrine, which protects actions related to petitioning government; laches; estoppel; waiver; license or implied license to use the articles; and the "first sale doctrine," which allows non-infringing uses of alleged copyrighted works after they have been legally acquired.

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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 contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

NEW BIO BUSINESS VENTURES

Biota Holdings, Nabi Biopharmaceuticals Plan to Form US Company

Australia's Biota Holdings Ltd. and Nabi Biopharmaceuticals have announced plans to form a combined company called Biota Pharmaceuticals headquartered in the United States and listed on Nasdaq. The move "is designed to achieve better value recognition and liquidity through a stronger U.S. shareholder base," Biota said. According to Biota, which develops anti-influenza drugs such as Relenza, the merger requires approval from both Biota and Nabi shareholders. Under the proposed merger, Biota shareholders would own about 74 percent of Biota Pharmaceuticals, while Nabi shareholders would own about 26 percent. *See The Wall Street Journal,* April 22, 2012; *Biota Press Release*, April 23, 2012.

INVESTOR NEWS

Forus Health Raises $5 Million for Eye-Disorder Screening

Forus Health Pvt. Ltd., a medical technology company based in Bangalore, India, has reportedly raised $5 million in Series A financing to manufacture and market its flagship diagnostic platform, a screening for eye disorders such as cataracts, glaucoma, diabetic retinopathy, and corneal damage. The funding comes from venture capital funds Accel Partners and IDG Ventures India.

The company's diagnostic platform, "3nethra," is designed as a "portable, low cost, non-mydriatic, non-invasive pre-screening ophthalmology solution" that can be operated by "minimally trained" technicians in remote areas with low doctor-to-patient ratios. "Technology can help us rethink health care delivery, and perhaps technology can transform health care from being cure-centric to prevention-centric and hence have a deeper impact in people's lives," said Forus President and Chief Technology Officer Shyam Vasudeva Rao. *See PRNewswire,* April 27, 2012.

BUSINESS CLIMATE

PhRMA Report Claims Almost 300 Vaccines in Development

American biopharmaceutical and research companies are developing nearly 300 vaccines for the prevention and treatment of a variety of diseases, according to a new report from the Pharmaceutical Research and Manufacturers of America (PhRMA). Under review by the Food and Drug Administration or in clinical trials, the vaccines include 170 for infectious diseases, 102 for cancers and eight for neurological disorders. "Vaccines are

one of the greatest achievements of biomedical science and public health," said PhRMA President and CEO John Castellani. "Over the past few decades, vaccinations have helped prevent and in some cases nearly eliminate contagious and deadly diseases affecting children and adults alike." Vaccines in development include those for pancreatic cancer, HIV, meningococcal disease, Alzheimer's disease, and malaria. *See PhRMA Press Release*, April 20, 2012.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

House Committee Approves $2.93 Billion for USPTO

The U.S. House of Representatives Committee on Appropriations has reportedly approved a **bill** that would give the U.S. Patent and Trademark Office (USPTO) $2.93 billion, a $255 million increase over the current fiscal year.

If approved by Congress to take effect for the fiscal year beginning October 2012, the funding represents an estimate of the fees the agency would collect under its America Invents Act authority. "The bill approved today makes responsible funding decisions to prioritize programs that . . . maintain the competitiveness of our businesses and industries, and scientific research to ensure American leads the world in innovation," said committee Chair Hal Rogers (R-Ky.). Under the proposed bill, fees collected by USPTO in excess of $2.93 billion would be deposited in a Patent and Trademark Fee Reserve Fund.

In a **report** accompanying the proposal, the committee asks USPTO for several things, including a report within 120 days of the bill's enactment showing patent applications by each state between fiscal years 2007 through 2011. It also requests estimates of the annual operating costs of USPTO's planned new satellite offices, the first of which is set to open no later than July in Detroit. It further calls on USPTO to prepare a report within 90 days of the bill's enactment that describes "its efforts to combat the malicious practice of trademark squatting." This occurs when companies register already USPTO-registered trademarked names in the hope of making large financial gains by selling the name back to the genuine trademark owner. *See House Appropriations Committee Press Release*, April 26, 2012.

White House Releases "National Bioeconomy Blueprint"

The White House Office of Science and Technology Policy (OSTP) has issued a **report** outlining "steps that agencies will take to drive the bioeconomy—economic activity powered by research and innovation in the biosciences." Titled the "National Bioeconomy Blueprint," the report also details governmental efforts to attain this goal.

The blueprint outlines five strategies to spur the U.S. bioeconomy: (i) support research and development investments; (ii) "facilitate the transition of

bioinventions from research lab to market"; (iii) "develop and reform regulations to reduce barriers, increase the speed and predictability of regulatory processes, and reduce costs while protecting human and environmental health"; (iv) "update training programs and align academic institution incentives with student training for national workforce needs"; and (v) "identify and support opportunities for the development of public-private partnerships and precompetitive collaborations—where competitors pool resources, knowledge, and expertise to learn from successes and failures."

"A more robust bioeconomy can enable Americans to live longer and healthier lives, develop new sources of bioenergy, address key environmental challenges, transform manufacturing processes, and increase the productivity and scope of the agricultural sector while generating new industries and occupational opportunities," said OSTP. *See OSTP Press Release*, April 26, 2012.

CRS Releases Nanotechnology Policy Primer

Noting that nanotechnology has the potential to achieve advances in renewable energy and detection and treatment technologies for cancer and other deadly diseases, the Congressional Research Service (CRS) has issued its most recent **report** addressing topics that may affect the country's ability to move nanotech from research laboratories to commercial products. Those topics include federal research and development investments under the National Nanotechnology Initiative; U.S. international competitiveness; environmental, health and safety issues; nanomanufacturing; and public attitudes toward, and understanding of, nanotechnology.

According to the report, "widespread uncertainty" continues as to the potential environmental, health and safety implications of nanotechnology, and bringing nanotech products "into safe, reliable, effective, and affordable commercial-scale production in a factory environment may require the development of new and unique technologies, tools, instruments, measurement science, and standards for nanomanufacturing." CRS also reports that more than 42 percent of Americans had never heard of nanotechnology as of 2007, while 6 percent indicated that they had "heard a lot." Those most likely to believe that the benefits of nanotechnology outweigh the risks were those earning more than $75,000 annually, men, people who had heard about it, and those between the ages of 35 and 64.

EC Scientific Committee Seeks Input on Nanosilver Safety

The European Commission's (EC's) Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) is **seeking** information on the health and environmental effects of nanosilver particles used in medical and consumer products.

Interested parties are invited to submit relevant information by June 4, 2012, particularly relating to the "nano" forms of silver. An EC review based on the information collected is expected by early 2013.

Commonly used for its antibacterial properties, nanosilver has come under scrutiny because "indirect adverse effects on human health may occur via an increasing resistance of micro-organisms against silver, including nanosilver and silver base compounds," limiting its usefulness in medical devices and other applications, according to SCENIHR. "Furthermore silver can be present in different forms (metallic—nanosized or not—and salts)," and it is unclear how these forms affect antimicrobial resistance and the healing process.

Malaysian Medical Device Laws Establish Formal Registration System

The Malaysian government adopted two laws this year that will replace a voluntary registration scheme for medical devices with mandatory requirements once they are fully implemented. Among other matters, Act No. 737 sets forth registration requirements for manufacturers and conformity assessment bodies. Failure to register a medical device under its terms can be punished with three years of imprisonment or fines of up to 200,000 ringgit (US$66,000). Full implementation will occur by 2014. Act No. 738 establishes the Medical Device Authority, which will oversee the industry and enforce the new medical device laws, and details its powers and obligations including the development of regulations to carry out the law.

LITIGATION

Eleventh Circuit Turns Aside FTC Challenge to Pay-for-Delay Deal

The Eleventh Circuit Court of Appeals has dismissed an antitrust action filed by the Federal Trade Commission (FTC) against a name-brand prescription drug manufacturer (the patent holder) and generic drug companies that entered into pay-for-delay agreements to settle patent infringement claims filed against the generic drug companies. *FTC v. Watson Pharm., Inc.*, No. 10-12729 (11th Cir., decided April 25, 2012). According to the court, FTC failed to state a claim on which relief could be granted because it alleged simply that the patent holder was "not likely to prevail" in the underlying infringement action. Under Eleventh Circuit precedent, FTC should have alleged that the settlement violated antitrust law because it "imposes an exclusion greater than that contained in the patent at issue," that is, the agreement prevents the generic drug makers from marketing a potentially infringing product to a greater degree than the existing patent would in the absence of the agreement.

Generic drug makers may obtain Food and Drug Administration approval to market a product that is chemically identical to a "pioneer drug" already approved and many do so by certifying that the "pioneer drug's patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug." Thereafter, the patent holder has the opportunity to file an infringement action against the generic drug maker.

Under a pay-for-delay agreement, used to settle an infringement action, the patent holder "pays an allegedly infringing generic drug company to delay entering the market until a specified date, thereby protecting the patent monopoly against a judgment that the patent is invalid or would not be infringed by the generic competitor." FTC has long maintained that these agreements, which it refers to as "reverse payment settlements," unfairly restrain trade in violation of federal antitrust laws in that they are tools the manufacturers use to protect monopoly profits "that the companies divvied up by means of payments from the patent holder to the generic manufacturers." FTC also contends that reverse payment settlements cost consumers some $3.5 billion annually due to higher drug prices.

Key to the Eleventh Circuit's approach is that a patent, by design, gives the holder a monopoly, and thus, an anticompetitive effect is already present. Without a court declaration that a patent is invalid or that a generic drug maker has not infringed the patent, the patent has inherent "potential exclusionary power," and a reverse settlement of patent litigation is immune from an antitrust attack unless the agreement excludes more competition that the patent has the potential to exclude. This would occur, for example, where a generic manufacturer agrees to refrain from ever marketing a generic version of the patented drug.

In this case, generic drug companies agreed not to market a gel used to treat the symptoms of low testosterone in men until 2015, i.e., five years before the patent expired, or unless another manufacturer launched a generic version before then. Generic drug companies also agreed to promote the branded drug to separate, specific markets. In return, the patent holder agreed to pay one generic drug maker $10 million per year for six years and an additional $2 million per year for backup manufacturing assistance. The patent holder also agreed to share some of its profits with another generic drug maker through September 2015, projecting payments between $19 million and $30 million per year. The drug had produced $1.8 billion in revenue from sales in the United States between 2000 and 2007, and it was estimated that the generic version, if sold for 25 percent of the price of the branded drug, would cut the patent holder's profits by $125 million per year.

The court refused FTC's invitation to adopt a rule "that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked

generic entry earlier than the agreed-upon entry date." According to the court, this approach "equates a likely result (failure of an infringement claim) with an actual result." In the court's view, "it is simply not true than an infringement claim that is 'likely' to fail actually will fail. . . . Rational parties settle to cap the cost of litigation and to avoid the chance of losing. Those motives exist not only for the side that is likely to lose but also for the side that is likely, but only likely, to win."

The court also rejected FTC's approach because it would "impose heavy burdens on the parties and courts. . . . In this case, assaying the infringement claim 'as of the time of settlement' would have required mining through mountains of evidence—when the lawsuit settled, more than 40 depositions had been taken and one side alone had produced more than 350,000 pages of documents. The settlement made that unnecessary, but the FTC's approach would put that burden back on the parties and the court, undo much of the benefit of settling patent litigation, and discourage settlements. Our legal system can ill afford that."

Further, because Congress has given the Federal Circuit Court of Appeals exclusive jurisdiction over appeals in patent cases, the court noted that the Eleventh and other non-specialized circuit courts "have no expertise or experience in the area. We are ill-equipped to make a judgment about the merits of a patent infringement claim, which is what we would have to do in order to decide how likely the claim was to prevail if it had been pursued to the end. The FTC's approach is in tension with Congress' decision to have appeals involving patent issues decided by the Federal Circuit."

Malpractice Claim Based on Patent Application Belongs in Federal Court

A Federal Circuit Court of Appeals panel has determined that (i) it had jurisdiction over an appeal from a district court order dismissing claims of fraud filed against lawyers who allegedly mishandled the plaintiff's patent application and (ii) because the statute of limitations was tolled while related malpractice litigation was pending before a California state court, the lawsuit was timely filed in federal court. ***Landmark Screens, LLC v. Morgan, Lewis, & Brockius, LLP*, No. 2011-1297 (Fed. Cir., decided April 23, 2012)**.

So ruling, the court reversed the district court's decision in part and remanded for further proceedings. A concurring judge, dissatisfied with the precedent on which the opinion was based, called for the case to be heard *en banc* to address the "disruption" resulting from Federal Circuit decisions giving the federal courts jurisdiction over actions in which "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims."

In this regard, Judge Kathleen O'Malley stated,

> In 2007, two years after the action was filed in state court, this court affected a sea change by announcing its assertion of jurisdiction over these types of state law claims. By then, the statute of limitations governing Landmark's malpractice claim had expired. A year after our decision in *Air Measurement,* appellees filed a motion to dismiss in state court, which was granted based on our case law. California has no savings statute, however, and, by statute, prohibits application of equitable tolling principles to malpractice claims, causing Landmark's malpractice claim to be lost forever. Thus, although Landmark filed its federal action on the same day the state court dismissed it, Landmark could no longer assert a malpractice claim against Kohler and MLB. In other words, a cause of action which—given the undisputed facts—was far from frivolous, which arises under and was governed by state law, and which all parties agreed for years had been properly asserted in California state court, was irretrievably lost by our disruption of the parties' well-settled expectations in this area.

(citations omitted).

As to the federal jurisdiction question, the Federal Circuit majority observed, "for Landmark to prevail on its claim for damages arising from the alleged fraud, under California law Landmark would have to prevail on its 'case within a case' and prove that but for the alleged fraud it would have obtained patent rights for its invention[, thus,] the patentability of Landmark's invention invokes patent law sufficiently to sustain district court jurisdiction." The court then applied California's equitable tolling jurisprudence to toll "the three-year statute of limitations for fraud claims during the time the case was pending in the state courts."

According to the court, the defendants had notice that the plaintiff was asserting the loss of its patent rights against them, and therefore, the defendants "have suffered no prejudice in their ability to gather evidence and prepare a defense since they were on notice of all key facts underlying Landmark's claims from the start of the state court action." The court also noted that Landmark acted reasonably and in good faith by first filing the complaint in state court, because, at that time, "there was ambiguity as to whether the suit belonged in state or federal court."

Biopharma Co. Seeks $90 Million for Tainted Raw Material from China

A biopharmaceutical company has sued companies in its supply chain, alleging they were negligent or vicariously liable for obtaining from China a raw material, contaminated with beef broth and avian products, for use in the creation of a bacterial master cell bank for the production of a biologic drug

that will be used in patients with acute spinal cord injury. *Bioaxone Biosciences, Inc. v. Nordion (US), Inc.*, No. 0:2012cv60739 (U.S. Dist. Ct., S.D. Fla., filed April 26, 2012).

The plaintiff alleges that the defendant knew that the cell bank specifically excluded the use of animal origin products and that source documents for the tainted kanamycin showed it was made in China. The plaintiff also alleges that the certificate of origin for the kanamycin states that it "contained beef extract and chicken feathers and that it was not for human use." According to the complaint, the defendants did not timely inform the plaintiff that the kanamycin used in the master cell bank contained animal-derived products that created "an unreasonably dangerous foreseeable risk of adventitious agents that cause disease in humans including, but not limited to, the development of BSE [bovine spongiform encephalopathy] in the patients to whom Cethrin would be administered."

Alleging that it has been unable to use the master cell bank in the development of its biologic drug for clinical trials, the plaintiff seeks damages in excess of $90 million.

NEWS BYTES

The Government Accountability Office issues a **report** indicating that the Food and Drug Administration has met most of its performance goals when reviewing prescription drug applications, including new drug applications and biologic license applications, received from fiscal year (FY) 2000 through FY 2010.

The U.S. Patent and Trademark Office requests **comments** on whether the current framework used to keep patent applications involving U.S. security interests secret should be extended to establish a similar screening program for patent applications disclosing subject matter deemed to be detrimental to national economic security. Also solicited are comments on the criteria used when determining national security-related secrecy orders. Comments are requested by June 19, 2012.

The Food and Drug Administration (FDA) publishes a **final rule** to amend regulations on the disqualification of clinical investigators. Under the changes, when the food and drug commissioner "determines that an investigator is ineligible to receive one kind of test article (drugs, devices or new animal drugs), the investigator also will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for other kinds of products regulated by FDA."

The Institute of Medicine releases a **report** titled "Ethical and Scientific Issues in Studying the Safety of Approved Drugs." It concludes that "FDA's current approach to drug oversight in the postmarket setting is not sufficiently

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systematic and does not ensure that it assesses the benefits and risks of drugs consistently over the drug's life cycle."

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Government Enforcement & Compliance Partner Robert McCully will serve as moderator of a panel discussion during AdvaMed's "2012 International Medical Device Industry Compliance Conference," scheduled for May 9-11, 2012, in Stockholm, Sweden. McCully's panel involves product distributors who will be discussing the latest compliance issues. Shook, Hardy & Bacon is a conference co-sponsor.

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.

The American Conference Institute's "3rd Advanced Forum on Biosimilars" will be held May 22-23, 2012, in New York City. Industry leaders will address the legal, regulatory and commercial aspects of "follow-on biologics," and a keynote address on implementing the biosimilar pathway will be presented by a Food and Drug Administration official.

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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.