Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

USPTO Seeks to Intervene in Publisher's Copyright Infringement Suit Against Law Firm

The U.S. Patent and Trademark Office (USPTO) has filed a motion to intervene, and an answer and counterclaim, in litigation brought by scientific-journal publishers against a law firm for alleged copyright infringement involving articles on prior art copied and submitted with its clients' patent applications. *John Wiley & Sons, Ltd. v. McDonnell Boehnen Hulbert & Berghoff LLP*, No. 12-C-1446 (U.S. Dist. Ct., N.D. Ill., E. Div., motion filed June 12, 2012). Details about this case and similar litigation filed in a federal court in Minnesota appear in Issue 31 of this *Bulletin*.

USPTO maintains that copying non-patent literature (NPL) and distributing it as "necessary and incidental to the filing and prosecution of a U.S. patent application . . . constitutes a fair use of such copyrighted works under 17 U.S.C. § 107, and therefore is not an infringement of copyright." According to USPTO, such use is necessary under federal law, serves the public interest and "has been part of the patent examination process since the Patent Act of 1836 conditioned the granting of patents only if the alleged invention was not previously 'described in any printed publication.'"

In its counterclaim, USPTO seeks a declaration that "the copying of copyrighted NPL and distribution thereof, which copying and/or distribution is necessary and incidental to the filing and prosecution of a U.S. patent application and/or the conduct of other USPTO proceedings concerning or relating to the scope or validity of any issued U.S. Patent, including copies of NPL actually submitted to the USPTO and copies of NPL initially considered but ultimately rejected for inclusion in submissions to the USPTO, by or at the direction of patent applicants, patentees, patent challengers, and/or their representatives, such as defendant McDonnell, constitutes a fair use of such copyrighted works . . . and therefore is not an infringement of copyright." USPTO also asks the court to dismiss the claims with prejudice.

Meanwhile, the journal publishers have filed a memorandum in opposition to a motion to dismiss filed in the copyright infringement suit pending in

Minnesota. *Am. Inst. of Physics v. Schwegman, Lundberg & Woessner*, No. 12 Civ. 528 (RHK-JJK) (U.S. Dist. Ct., D. Minn., memorandum filed June 5, 2012). The publishers contend that they have not failed to state a claim and they have met the pleading standard established under *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544 (2007), and *Ashcroft v. Iqbal,* 556 U.S. 662 (2009). While they state that it was not necessary for them to attach copies of copyright registration certificates to their complaint to properly plead copyright ownership, they attach such certificates to their memorandum.

The publishers also argue that it is reasonable for the court to infer from their complaint that when the law firms submitted copyrighted articles with their patent applications to USPTO they also "made additional copies . . . for their internal use," and they "copied other copyrighted works of the Publishers [in] connection with Patent Application No. 12/395/592 and their patent prosecution practice generally, but did not ultimately cite or provide those to [USPTO]." According to the publishers, they were not required to plead "the precise time of the copying and the individuals who participated in it, because that copying occurred behind closed doors at Schwegman." The publishers further argue that they properly alleged "a distribution to the public" by stating in their complaint that "defendants delivered an unauthorized copy of plaintiffs' copyrighted articles to [USPTO]. That delivery . . . constitutes a 'public' distribution of that copy within the meaning of 17 U.S.C. § 106(3)."

The memorandum concludes by contending that the lawsuit is timely because the statute of limitations began to run not when the copying occurred, but when the "infringing acts of copying" became publicly available, i.e., when the articles were submitted on or about November 17, 2010, and became a public record.

Federal Circuit Refuses to Consider Standing/Mootness Issue in *Myriad Genetics*

The Federal Circuit Court of Appeals has issued a non-precedential order declining Myriad Genetics' invitation to revisit whether the plaintiff has standing, that is, a redressable legal interest in maintaining the lawsuit, and will thus consider, on remand from the U.S. Supreme Court, whether isolated DNA claims and method claims are patent-eligible under *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). *Ass'n for Molecular Pathology v. USPTO*, No. 2010-1406 (Fed. Cir., order entered June 11, 2012). The briefing deadline was June 15, and oral argument on the merits has been scheduled for July 20.

Myriad Genetics argues in its supplemental brief that *Mayo* "has no effect on the Court's prior judgment that these claims are patent-eligible." Specifically, Myriad contends that *Mayo*, because it addressed method patent claims, does not apply to its isolated DNA claims, which are composition claims that

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are the product of human invention. As to the method claims in its patents, Myriad urges the court to find that its earlier decision is final and undisturbed by the U.S. Supreme Court's ruling because the petition for certiorari to the Court did not seek review of the Federal Circuit's ruling on this issue.

The American Civil Liberties Union (ACLU) states in its brief on behalf of the plaintiffs-appellees that "*Mayo* gave new vigor to three principles for determining whether a law/product of nature has been 'transformed' into something patentable. First, courts must examine whether the patent claims preempt what is unpatentable—such as laws and products of nature—a question that was unaddressed by the original majority or concurring opinions. Second, the Court makes clear that what is patented must be based on an 'inventive concept' or 'add enough' to the natural phenomena, or as it has said in other cases, have 'markedly different characteristics from any found in nature.' Under *Mayo* and previous Supreme Court precedent, trivial chemical transformations cannot meet this test. Third, the Court held that the role of the courts is to decide whether claims fall within the law/product of nature doctrine without regard to industry reliance and the Patent Office's approval of patents." The ACLU concludes, "A fair application of these three principles to this case should lead this court to issue a new opinion and judgment affirming the district court as to the isolated DNA claims and [method] claim 20 of the '282 patent."

INVESTOR NEWS

Rhythm Scores $25 Million for Diabetes and Obesity Drugs

Rhythm Pharmaceuticals of Boston, Massachusetts, has reportedly raised $25 million in Series B financing for diabetes and obesity therapeutics, bringing the total capital raised in the round to $65 million. According to the company, all existing investors participated, including MPM Capital, New Enterprise Associates and Third Rock Ventures, in addition to new investor Ipsen.

The company plans to use the financing to advance its small-peptide therapeutics for metabolic diseases through Phase 2 clinical trials. The drugs are RM-131, a ghrelin agonist for treating diabetic gastroparesis, and RM-493, an agonist of the melanocortin 4 receptor (MC4R), which is in Phase 1 clinical trials for obesity and diabetes treatment. "These programs have great potential for addressing major unmet needs in diabetes, obesity and gastrointestinal functional disorders, and this financing supports a broad and thorough Phase 2 development program for both drugs," said Rhythm's Founder and President Bart Henderson. *See Rhythm Pharmaceuticals Press Release,* June 13, 2012.

Blaze Bioscience Secures $5 Million to Advance "Tumor Paint" Technology

Seattle-based Blaze Bioscience has reportedly raised $5 million in Series A financing to advance its "Tumor Paint" technology. According to the company, the technology provides "real-time, high-resolution intraoperative visualization of cancer cells" and allows surgeons to see and remove cancerous tissue that might have otherwise gone undetected, while sparing critical normal tissue. Under development for multiple solid tumors, the first Tumor Paint product candidate combines a targeting peptide and fluorescent beacon.

"This funding is a significant milestone for Blaze Bioscience," said President and CEO Heather Franklin. "It will allow the company to transition from the seed stage to full execution mode moving Tumor Paint into development, including product scale up and toxicology studies, on schedule." Added Jim Olson, co-founder and board member: "We remain inspired by the needs of the pediatric brain cancer patients for whom the technology was developed." *See Blaze Bioscience Press Release,* June 8, 2012.

Igenica Closes $33 Million in Series C Financing for Cancer Therapeutics

Igenica Inc., a biopharmaceutical company seeking to discover and develop antibodies for cancer treatment, has reportedly raised $33 million in Series C funding. Led by new investor Third Rock Ventures, participation also came from existing investors such as The Column Group, Orbimed Advisors and 5AM Ventures. Since its inception in January 2009, Igenica has evidently raised $55 million.

According to the California-based company, the latest financing will be used to advance its monoclonal antibody pipeline toward clinical trials. It will also develop "sTAg," a method to discover and prioritize novel tumor antigens, and "iTAb," a "functional in vivo antibody screening approach." *See Igenica Press Release,* June 12, 2012.

VLST Secures $5 Million to Develop Autoimmune and Inflammatory Disease Treatments

Seattle-based VLST Corp. has reportedly raised an additional $5 million in Series B venture capital funding, with the financing possibly expanding to $15 million, according to a U.S. Securities and Exchange Commission filing. Investors include OVP Venture Partners, Arch Venture Partners, WRF Capital, and Versant Ventures. VLST has evidently raised $50 million since its 2004 startup at Accelerator Corp., a privately-held biotechnology investment and development company.

The latest funding will be used for VLST's research and development programs for the treatment of autoimmune and inflammatory diseases. "We are continuing to advance our internal programs, and like everybody else,

we have been scouring the environment to look for any potential, relevant in-licensing opportunities," said Marty Simonetti, the company's chief executive officer. "We wanted to make sure we had the necessary capital to do both if we needed." *See Xconomy*, June 14, 2012.

GeneNews Completes $2.5 Million in "Rights Offering"

GeneNews Limited, an emerging molecular diagnostic company based in Toronto, Canada, has reportedly completed a $2.5-million "Rights Offering" to holders of its common shares by issuing 23,224,529 shares at 11 cents per share. According to the company, its patented core platform technology, the Sentinel Principle®, can detect a range of diseases or medical conditions, such as cancer, arthritis, cardiovascular disease, and neurological disorders, from a simple blood sample. The company plans to apply the technology to expand the commercialization of its lead product ColonSentry, which can assess colorectal cancer risk without a colonoscopy and was recently launched in New York and New Jersey. *See GeneNews Press Release*, June 12, 2012.

Wellcome Trust Provides $4 Million to University for *Salmonella* Vaccine

The University of Maryland School of Medicine's Center for Vaccine Development has reportedly received a $4-million grant from the Wellcome Trust to develop a vaccine for the prevention of non-typhoidal *Salmonella*, a potentially lethal infectious disease common in sub-Saharan Africa. The center, which has apparently developed a reputation for creating and testing vaccines against bacterial diseases, such as cholera and typhoid fever, will collaborate with Hyderabad, India, partner Bharat Biotech in pre-clinical and clinical studies. *See The Economic Times, Baltimore Business Journal* and *Newswise,* June 18, 2012

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Biotech Life Sciences Trade Mission to Australia Announced

The U.S. Department of Commerce, International Trade Administration and U.S. and Foreign Commercial Service have **announced** an October 29-November 2, 2012, Biotech Life Sciences trade mission to Australia. Participants are expected to include a variety of U.S. biotechnology and life science firm representatives who will visit prominent biotech organizations, attend government meetings and participate in briefings and receptions during Melbourne's AusBiotech National Conference, which purportedly attracts biotech companies in the medical, diagnostics, agriculture, industrial, and environmental sectors.

The trade mission's goals are to (i) "increase U.S. exports to Australia," (ii) "introduce U.S. participants to potential strategic partners," (iii) "introduce U.S. participants to industry and government officials in Australia to learn about various opportunities," and (iv) "educate the participants about trade policy and regulatory matters involved in doing business in Australia." Applications for the mission must be submitted by July 15, 2012, and selection decisions will be made on a rolling basis until 10 to 12 participants have been selected. *See Federal Register,* June 13, 2012.

China Amends IP Law to Facilitate Copying of Protected Medicines

According to a news source, China has adopted intellectual property law amendments that will allow Beijing to issue compulsory licenses to eligible companies to produce generic drugs, even when the branded drugs are still under patent protection, during state emergencies, under unusual circumstances or in the public interest. Eligible drug manufacturers would also be permitted to export these medicines to other countries. According to some legal experts, this legislation is within the limits of international trade agreements and comports with similar action taken in Malaysia, Indonesia, Thailand, and India. *See Reuters*, June 8, 2012.

India Prepares Draft Guidelines for Biosimilar Drugs

India's Department of Biotechnology has reportedly prepared draft guidelines for biosimilar drugs in consultation with industry stakeholders. According to a news source, the lack of standard regulations for biotech generic drugs led to drafting specific guidelines for pre-marketing and post-marketing data separate from guidelines for pre-clinical and clinical trials for the drugs. The document will apparently be available soon for public comment.

Currently, biosimilars in India are approved based on general guidelines, a situation that has apparently resulted in some drugs receiving approval without clinical trials conducted on sufficient numbers of patients. "There is a need for tailor-made guidelines for clinical trials as well as for post-marketing surveillance of biosimilars," a health ministry official was quoted as saying. "We have prepared this draft after considering all the factors so that it helps in creating and maintaining the goodwill of the industry even at the international level."

According to Panacea Biotec's Joint Managing Director Rajesh Jain, the proposed guidelines are expected to give more credibility to drugs developed in India. "The aim is to harmonize the industry and ensure that Indian biotechnology companies and their products are at par with other international drugs," Jain said. *See Business Standard,* June 10, 2012.

Comments Sought on Class B Medical Device Registration Guidance in Singapore

Singapore's Health Sciences Authority is requesting stakeholder comments by June 28, 2012, on new guidance pertaining to the registration of Class B medical devices. The guidance, which was drafted following the April 20 announcement of enhancements to Singapore's medical device regulatory framework, provides additional information about two new evaluation routes for registration: expedited and immediate. The new draft guidance also includes information about eligibility criteria and submission requirements for each evaluation route, as well as "processing flow." Class B medical devices "are typically of low-moderate risk and include devices such as hypodermic needles, suction apparatus, pregnancy test kits, and ultrasound imaging equipment."

LITIGATION

Court Watchers Awaiting SCOTUS Ruling on Health-Care Law, Implications for Biosimilars

The U.S. Supreme Court's highly anticipated decision on the validity of the health-care reform law could have a significant impact on the approval pathway for biosimilar drugs because the Patient Protection and Affordable Care Act included the provisions giving the Food and Drug Administration (FDA) authority to review and approve biosimilars. If the Court decides that the challenged parts of law are unconstitutional and that its separate provisions cannot stand on their own, the entire law will be ruled invalid and FDA will be unable to accept applications to approve biosimilars. A ruling is expected by the end of June 2012. *See Law360*, June 14, 2012.

All Brazilian Soy Farmers Could Recover Against Monsanto in GM Royalty Dispute

Brazil's high court has reportedly issued a ruling indicating that a lower court decision on whether Monsanto can continue to require soy farmers to pay royalties for growing soy beans from the seed saved from genetically modified soy crops, grown from seed purchased from the company, will have nationwide, rather than local effect.

Monsanto apparently charges soy farmers 2 percent of their sales of Roundup Ready® soy beans, claiming that most Brazilian farmers use smuggled seeds. The farmers counter that 70 percent of farmers buy their Roundup Ready® seeds legally. In April 2012, a judge in Rio Grande do Sul reportedly determined that the company's levy was illegal given that the patents have expired and that Brazilian law allows farmers to use their crop as seed without paying the seed provider. The court further ordered the company to stop collecting royalties and to pay back royalties collected since 2004 or a minimum of US$2 billion. Monsanto has appealed that ruling.

The Supreme Court's decision on the scope of the lower court's decision could increase the royalty refund to US$7.5 billion, if the April decision is ultimately affirmed. *See Nature.com*, June 15, 2012; *FoodNavigator.com*, June 18, 2012.

Federal Circuit Panel Returns to Gore-Tex Graft Dispute, Clarifies Willfulness Standard for Enhanced Damages

The Federal Circuit Court of Appeals has vacated parts of its February 2012 decision in a long-running patent dispute over a prosthetic vascular graft and remanded the matter for the district court to address the objective prong of the willfulness standard and reconsider its denial of W.L. Gore's motion for judgment as a matter of law of no willful infringement. ***Bard Peripheral Vascular, Inc. v. W.L. Gore & Assoc., Inc.*, No. 2010-1510 (Fed. Cir., decided June 14, 2012)**. The appellate court's earlier ruling, which upheld a district court's decision to enhance the damages verdict against W.L. Gore for willful infringement, is discussed in **Issue 30** of this *Bulletin*.

The Federal Circuit granted W.L. Gore's request for rehearing to address "a new question regarding the nature of the objective inquiry from *In re Seagate Technology, LLC*." Under *Seagate*, a two-prong test is used to establish the requisite level of recklessness to justify the imposition of civil punitive damages. Thus, "a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." Once that threshold objective standard is satisfied, "the patentee must also demonstrate that this objectively defined risk . . . was either known or so obvious that it should have been known to the accused infringer."

On rehearing, the Federal Circuit agreed that the trial court had failed to consider the objective prong of the standard and further held that "the threshold objective prong of the willfulness standard enunciated in *Seagate* is a question of law based on underlying mixed questions of law and fact and is subject to *de novo* review." While the trial court may "allow the jury to determine the underlying facts relevant to the defense in the first instance, for example, the questions of anticipation or obviousness, . . . the ultimate legal question of whether a reasonable person would have considered there to be a high likelihood of infringement of a valid patent should always be decided as a matter of law by the judge."

In a dissenting opinion, Judge Pauline Newman would have ruled on the matter under the newly enunciated standard, finding a remand unnecessary. She contended that willful infringement was not supportable on the record, but, in the alternative, would have remanded for retrial of the entire case.

Fourth Circuit Joins Others to Adopt Predicate-Act Doctrine for Foreign Copyright Infringement

The Fourth Circuit Court of Appeals has adopted the predicate-act doctrine "which posits that a plaintiff may collect damages from foreign violations of the Copyright Act so long as the foreign conduct stems from a domestic infringement." *Tire Eng'g & Distrib. v. Shandong Linglong Rubber Co., Ltd.*, Nos. 10-2271, -2273, -2321 (4th Cir., decided June 6, 2012). So ruling, the court declined to limit the doctrine's application "to cases where a domestic violation is not time barred" and also decided that the Lanham Act did not apply to the extraterritorial acts alleged by the plaintiff, because the defendants' "trademark infringement lacks a sufficient effect on U.S. commerce."

The Second and Ninth Circuits have also adopted the doctrine, while the Sixth and Federal Circuits have, according to the court, recognized its validity. The Fourth Circuit found that "[t]he doctrine strikes the appropriate balance between competing concerns, protecting aggrieved plaintiffs from savvy defendants while also safeguarding a defendant's freedom from stale claims. Absent the predicate-act doctrine, a defendant could convert a plaintiff's intellectual property in the United States, wait for the Copyright Act's three-year statute of limitations to expire, and then reproduce the property abroad with impunity. Such a result would jeopardize intellectual property rights and subvert Congress's goals."

Upholding the jury's $26-million damages award, the court found that activities occurring in the United States were sufficient under the predicate-act doctrine to constitute a violation of the Copyright Act. According to the court, former and current employees of the plaintiff, a domestic producer of mining tires, held a meeting in Virginia with a foreign company representative to discuss prospects for its entry into the mining-tire business. The current employee stole the plaintiff's blueprints and provided them to the foreign company. He also worked from his home in Virginia on a business plan to sell infringing tires and was offered employment with the foreign company. The Virginia home was referred to in correspondence as "a satellite office" of the foreign company. The tires were then manufactured by a China-based company and sold to the plaintiff's former customers. Based on this evidence, unlawful conversion of the blueprints in the United States and their unauthorized reproduction, the court found a domestic violation of the Copyright Act as well as damages from extraterritorial exploitation of this infringing conduct.

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NEWS BYTES

The Food and Drug Administration seeks comments by August 13, 2012, on draft and revised draft guidances for industry describing product-specific bioequivalence recommendations regarding the design of studies to support abbreviated new drug applications.

The Food and Drug Administration (FDA) issues a guidance for small businesses titled "Toll-Free Number Labeling and Related Requirements for Over-the-Counter and Prescription Drugs Marketed with Approved Applications: Small Entity Compliance Guide." FDA welcomes comments at any time.

The Institute of Medicine's Board on Health Sciences Policy announces a July 17-18, 2012, Washington, D.C., workshop titled "Assessing the Economics of Genomic Medicine." The workshop's goal is advancing "discussions around the clinical integration of genomic applications."

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