Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Science Publishers Voluntarily Dismiss Part of Copyright Infringement Case Against Law Firm

The companies that claim law firms violate their copyrights in scientific articles when the firms submit copies of the articles with patent applications to the U.S. Patent and Trademark Office have sought leave to amend their complaint by withdrawing these claims but will move forward with claims that additional copies the firms make infringe the companies' copyrights. *Am. Inst. of Physics v. Schwegman, Lundbert & Wessner, P.A.*, No. 0:12-cv-00528-RHK-JJK (U.S. Dist. Ct., D. Minn., pleading filed September 14, 2012). Further details about this litigation appear in issues 31 and 34 of this *Bulletin*.

The publishers state, "Plaintiffs now seek to file an amended complaint that continues to allege that Defendants have engaged in unauthorized copying in connection with their internal research, but does not allege that this unauthorized copying includes (i) making such copies of a copyrighted work for submission to the PTO as may be required by the rules and regulations of the PTO, (ii) transmitting such copies to the PTO, or (iii) making an archival copy of that work transmitted to the PTO for Defendants' internal file to document what has been transmitted. To be clear, however, such submissions to the PTO may be evidence of broader use and circulation, which would be relevant to these proceedings."

The pleading follows the motion to intervene and counterclaim filed by the U.S. Patent and Trademark Office on July 2, 2012, the same day that the court denied the defendants' motion to dismiss, in which the government sought a declaration that copying or distribution of copyrighted non-patent literature as "necessary and incidental to the filing and prosecution of a U.S. patent application" does not infringe copyright. The plaintiffs contend that their amended complaint would not cause any party to suffer prejudice because preliminary discovery alone has occurred since the suit was filed and "[t]he proposed amended complaint does not expand the complaint except to add additional copyrights to Schedule A, and to add as an additional Plaintiff an affiliate of Wiley which owns one copyright." The U.S. Patent and Trademark Office has not, as yet, according to the pleading "served or responded to any discovery, beyond a voluntary disclosure."

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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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Parties to Patent Reform Law Challenge Exchange Pleadings

The U.S. Patent and Trademark Office (USPTO) has filed its opposition to a lawsuit challenging the constitutionality of the Leahy-Smith America Invents Act (AIA), and the plaintiffs have filed their reply to the opposition. *MadStad Eng'g v. USPTO*, No. 8:12-CV-01589-SDM-MAP (U.S. Dist. Ct., M.D. Fla., Tampa Div., reply filed September 13, 2012). Details about the litigation appear in issue 41 of this *Bulletin*.

The government argues that the plaintiff, a "garage inventor" who holds a patent on a motorcycle windshield, has failed to show irreparable harm if the AIA and its new first-to-file patent system take effect, as scheduled, in March 2013. Because irreparable harm is needed to justify a preliminary injunction, the government contends that such relief is unwarranted. The government also forcefully argues that the AIA awards patents to "inventors" only and thus, that "first filers may only receive patents if they are in fact inventors." The government further notes that "derivation proceedings replace interferences" under the patent reforms; the derivation proceedings will "determine whether one applicant or patentee derived—i.e., stole—the claimed invention from a true inventor and then applied for a patent, without the inventor's authorization, before the inventor."

Arguing that none of their injuries are speculative, the plaintiffs argue that they have incurred significant expenses to guard the secrecy of work intended to lead to new inventions, in a reversal of previous practice where inventions could be shown to potential investors or partners and otherwise shared. The plaintiffs also argue that "the AIA encourages theft by increasing the value of stolen IP (as shown by overseas experience)." The plaintiffs insist that the AIA has eliminated any inventorship requirement and, by doing so, is unconstitutional "because the Patent Clause does indeed constrain Congress to granting patents only to whom the Government calls 'first inventors' (and what the Constitution calls 'inventors')."

By deleting section 102(f) of the Patent Act, "which formerly made inventorship a condition of patentability," Congress purportedly "allows a statutorily valid (although not a constitutionally valid) patent to issue to one who is not an inventor at all," according to the plaintiffs. They also maintain that derivation proceedings will not identify "the first true inventor"; rather, the proceedings will determine whether "the first-filer stole or copied the invention. This is not an inventorship requirement." The plaintiffs further claim that the "Government apparently believes that losing the race to the [U.S. Patent and Trademark Office] is equivalent to 'suppressing' or 'withholding' a patent." They cite cases allowing good faith delays in filing patent applications to allow for testing and perfecting inventions.

Study Shows Rise in Biotech Patent Litigation

PricewaterhouseCoopers LLP has released its "2012 Patent Litigation Study," which shows that the 4,105 patent lawsuits filed in 2011 marked a high point and a 22-percent increase from the previous year. Biotechnology cases have increased significantly since 1995-2000, when 40 were filed, with 112 filed during the 2006-2011 period. The study also showed a high correlation between patent cases filed and patents granted by the U.S. Patent and Trademark Office. Other findings include that (i) median damages awarded in the most recent five-year period (2006-2011) are less than half the median award between 2001 and 2005; (ii) median damage awards for non-practicing entities continue to outpace those of practicing entities, a trend that began in 2001; (iii) the largest historical awards are rarely upheld on appeal; and (iv) "reasonable royalties are the predominant measure of damages; price erosion is rare."

This year's report includes a section on ANDA (abbreviated new drug application)-related filings, that is, litigation resulting "from a generic drug manufacturer's filing with the Food and Drug Administration an ANDA paragraph IV certification, which effectively challenges a brand drug manufacturer's patent(s)." The number of court rulings in ANDA litigation increased to 70 in 2006-2011 compared to 16 in 1995-2000. As the study notes, "the economic ramifications of ANDA litigation are significant due to the potential for lost patent protection of highly profitable brand name drugs. In addition, the first generic filer of a successful patent challenge is awarded a period of exclusivity in the generic drug market." The report also shows which are the favored ANDA federal district courts, historical success rates and top ANDA litigants.

NEW BIO BUSINESS VENTURES

DNA-Sequencing Firm Acquired in $117.6-Million Deal

A struggling Silicon Valley DNA-sequencing company has reportedly agreed to be acquired by a Chinese company, said to be the largest sequencing operation in the world. Complete Genomics, which has evidently charged too little, at $5,000 per human genome for large orders, to make a profit, will be acquired by BGI-Shenzhen for $117.6 million. BGI-Shenzhen CEO Wang Jun reportedly indicated that Complete Genomics, which will "fit well with our research and business requirements," will continue to operate separately. Antitrust clearance and a national security review in the United States are needed before the deal can be closed, and certain Chinese government authorities will also scrutinize the agreement. *See The New York Times DealBook*, September 17, 2012.

U.S. and Chinese Biotechs Enter Product Development and Distribution Partnership

U.S.-based Life Technologies Corp. has reportedly partnered with Sino Biological Inc. to distribute the Chinese company's portfolio of recombinant proteins, antibodies and test kits as well as jointly develop new products.

The collaboration will allow Life Technologies to distribute more than 6,000 human-derived proteins and antibodies in the global marketplace. The companies anticipate leveraging their respective research and development synergies "to introduce innovative products more quickly." Sino Biological develops biological tools for scientists and has commercialized more than 10,000 products. Life Technologies also supplies research laboratories, focusing on agricultural biotechnology, translational research, molecular medicine and diagnostics, stem cell-based therapies, forensics, food safety, and animal health. *See PR Newswire*, August 30, 2012.

OmniRat™ Antibody Collaboration Announced

WuXi PharmaTech has reportedly entered an agreement with Open Monoclonal Technology, Inc. (OMT), which will allow the use of OMT's transgenic rats as a platform for the development of human therapeutic antibodies. WuXi, with operations in China and the United States, provides pharmaceutical, biotechnology and medical device companies with a portfolio of laboratory and manufacturing services. OMT's OmniRat™ technology, by generating human antibodies with specificity, affinity and manufacturability, will apparently give WuXi the ability to "expand its service offerings in discovery of fully human antibodies," according to WuXi COO and CFO Edward Hu. OMT founder and CEO Roland Buelow said, "Under the collaboration, OMT can leverage WuXi's expertise and capacity to create novel therapeutic candidates for its biopharmaceutical customers and apply OMT's technology to an ever-broadening base of drug candidates." *See PR Newswire*, September 4, 2012.

INVESTOR NEWS

$5.3 Million Financing to Fund Connective Tissue Disease Diagnostics

Specialty diagnostics company Exagen Diagnostics Inc. has announced the successful execution of a $5.3-million "capital raise" led by Tullis Health Investors with participation by Sun Mountain Capital, Cottonwood Technology Fund, Mesa Verde Venture Partners, and Epic Ventures. Exagen president and CEO Ron Rocca stated, "We are committed to the expansion of our three marketed rheumatology brands, Avise SLE, Avise PG and Avise MCV, as well as the development of several important near-term pipeline products that will assist physicians with the diagnosis and treatment of rheumatologic disorders. It's our goal to arm physicians with the best tools available to help these patients." Apparently, connective tissue diseases are difficult to correctly diagnose. *See Exagen Diagnostics Inc. Press Release*, September 10, 2012.

Biomass Crop Developer Raises $15 Million

Agrivida, Inc., a Medford, Massachusetts-based company focusing on plant biotechnology to create corn and other crops that can readily be converted

into biofuel, has reportedly raised $15 million in a Series C financing round to further develop and commercialize its INzyme™ platform. The company has apparently been working since 2003 to bioengineer a type of corn using a patented peptide technology that attaches to an enzyme which can be switched off to allow corn to grow normally and later switched on to allow the cell walls in stalks and leaves to be easily broken down.

According to a company news release, "[e]arlier this year, Agrivida launched its first significant field production of INzyme™ materials in U.S. Department of Agriculture-regulated trials. Materials from these trials will be used in larger-scale agricultural and industrial processing trials, to refine both field performance and processing characteristics of Agrivida-modified feedstocks." *See Agrivida, Inc. Press Release*, September 10, 2012.

Biopharmaceutical Secures $4.6 Million to Develop Hepatitis Drugs

According to a news source, Palo Alto, California-based Eiger Biopharmaceuticals has secured most of a targeted $5-million financing round and is expected to use it to continue developing and testing drug candidates to treat hepatitis D and hepatitis C. Eiger apparently uses prenylation inhibitors to block replication of the hepatitis D life cycle; while hepatitis D generally resolves without intervention, it can increase mortality by a factor of 10 when it occurs in those afflicted with hepatitis B as compared to those with hepatitis B alone. The World Health Organization estimates that up to 3 percent of the world's population is infected with hepatitis C, and annual drug sales to treat it total $5 billion. *See MedCity News*, September 13, 2012.

BUSINESS CLIMATE

New Biotech Jobs in Massachusetts Outpace Hiring in Other Industries

According to a new Massachusetts Biotechnology Council report, while hiring in the biotech industry has not fully recovered from the recession, the industry is adding jobs faster in Massachusetts than the state's economy as a whole, and the state has added more jobs in biotechnology research than any other state between 2007 and 2011. Venture capital investments in Massachusetts biotechs apparently reached an all-time high in 2011, at $1.071 billion. The state's share of biotechnology investments still exceeds 20 percent, although 2010 marked a high with 23.1 percent. As compared to other biotechnology centers in the United States, Massachusetts saw a greater percentage of total venture capital investments in start-up and early-stage companies. The report also notes that drug companies headquartered in Massachusetts have 955 drug candidates at some stage of research and development.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

CRS Releases Report on "Patent Trolls" Debate

The Congressional Research Service has released a report titled "An Overview of the 'Patent Trolls' Debate," that reviews the controversy over litigation filed by non-practicing entities "and their effect on innovation, examines the reasons for the rise in PAE [patent assertion entity] litigation, and explores the legislative options available to Congress if it decides that these are issues that should be addressed."

Among other matters, the report notes that 92 percent of such litigation fails on the merits, but that most cases are resolved through settlements because defendants view patent litigation as "risky, disruptive, and expensive, regardless of the merits; and many PAEs set royalty demands strategically well below litigation costs to make the business decision to settle an obvious one." Still, according to the report, non-practicing entities "generated $29 billion in revenues from defendants and licensees in 2011, a 400 percent increase over $7 billion in 2005."

Comments Sought on Guidelines for Nanotoxicology Research Papers

Nature Nanotechnology editors have initiated an effort to develop guidelines that would apply to researchers submitting papers on the toxicity of various nanomaterials. A dialogue on the matter was scheduled for the 6th Annual Conference on Nanotoxicology held September 4-7, 2012, in Beijing. According to a journal editorial, "few studies offer consistent results that are of value, and it is difficult to compare studies because they are often carried out using poorly characterized nanomaterials and arbitrary experimental conditions." Written comments are requested by November 30.

An accompanying commentary examined "published studies that report *in vitro* cytotoxicity of silica nanoparticles (SNPs)—a material that is widely used and studied by many, including us—to show the gaps in knowledge and the need to better focus our research efforts." Françoise Schrurs & Dominique Lison, "Focusing the research efforts," *Nature Nanotechnology*, September 2012. According to the authors, even the most basic questions, such as "Are SNPs more cytotoxic than their larger counterparts?," "Do SNPs penetrate into cells?" and "Which properties of SNPs drive their cytotoxic activity?," do not have clear answers despite the 38 papers eligible for analysis.

India's Guidance for Biosimilar Drugs Draws Cautious Industry Welcome

According to a news source, industry has given India's new guidelines for biosimilar drugs, launched August 15, 2012, a "cautious welcome." The companies are concerned that a requirement for comparative clinical trials will affect their budget allocations, but also know that "[a]pproval 'without involved clinical trials' is possible if manufacturers prove close similarity to [a] reference

product, and show consistency in production process." The guidelines were developed with input from stakeholders, and drafters took European and U.S. guidelines into consideration while drafting. The guidelines apparently require that biosimilar manufacturers prove similarity to a reference biologic already approved in the country and sold for at least four years in a regulated market. Safety, efficacy and quality must be comparable to the innovator drug as shown by analytical and clinical trials. *See Nature Nanotechnology*, September 2012.

LITIGATION

Location of Outside Patent Counsel May Not Subject Company to State Jurisdiction

A federal court in Massachusetts has dismissed a suit seeking a declaration of non-infringement filed by a Massachusetts company against a Texas-based company, finding that the defendant lacked sufficient contacts with Massachusetts to allow the court to exercise jurisdiction over it. *TomTom, Inc. v. Norman IP Holdings, LLC*, No. 12-10348-FDS (U.S. Dist. Ct., D. Mass., decided September 4, 2012). So ruling, the court rejected the plaintiff's argument that the Texas company established sufficient contacts with Massachusetts by retaining a Massachusetts-based law firm to represent it in patent enforcement actions filed in other states.

TomTom had filed the declaratory judgment action against Norman after Norman brought a patent infringement action against TomTom in Texas. Among other matters, TomTom claimed that Norman was a non-practicing entity created solely to enforce patent licenses through litigation and that its business-related activity in Massachusetts consisted of initiating infringement litigation against TomTom. TomTom further contended that Norman's retention of Massachusetts-based counsel also gave it sufficient business contacts with the Commonwealth.

According to the court, "[t]he cases TomTom cites in its objection to the [magistrate's] Report and Recommendation stand only for the proposition that a patentee *may* establish minimum contacts in a state when it hires counsel for the enforcement or defense of the patent in that state's courts. … Here, all of Norman's enforcement actions have been commenced elsewhere. Those actions do not constitute sufficient minimum contacts with Massachusetts to support the exercise of personal jurisdiction."

Induced-Infringement Ruling Splits En Banc Federal Circuit Court of Appeals

In a ruling that departs from prior case law, a bare majority of the Federal Circuit Court of Appeals has determined that someone who induces others to infringe a patent can be held liable to the patent holder; the court thus overturned prior inconsistent decisions holding that a single entity must be liable for direct infringement in order for a party to be liable for induced infringement under 35

U.S.C. § 271(b). *Akamai Techs., Inc. v. Limelight Networks, Inc.*, Nos. 2009-1372, -1380, -1416, -1417; *McKesson Techs., Inc. v. Epic Sys. Corp.*, No. 2010-1291 (Fed. Cir., decided August 31, 2012).

Akamai Technologies owns a method patent for the efficient delivery of web content. It consists of placing a content provider's content on a set of replicated servers and modifying the content provider's Web page to instruct Web browsers to retrieve the content from the servers. Limelight maintains a server network that allows for efficient content delivery by placing some content elements on its servers. Limelight does not modify the content providers' Web pages but instructs customers on the steps needed to do so.

McKesson Information owns a patent for a method of electronic communication between health-care providers and patients. Epic Systems licenses its software to health-care organizations; the software includes an application that permits health-care providers to communicate electronically with patients. Epic Systems does not perform any of the patent steps; those steps are instead "divided between patients, who initiate communications, and health-care providers, who perform the remainder of the steps."

Thus, no single "induced" entity commits all of the infringing acts or steps in either case. Finding nothing in the statute indicating that "infringement" is limited to "infringement" by a single entity, and finding that the effect on the patent holder is the same whether more than one party carries out all the steps of a method patent, the court held that while "all the steps of a claimed method must be performed in order to find induced infringement, … it is not necessary to prove that all of the steps were committed by a single entity." The court examined tort law principles, the legislative history and carefully distinguished related cases to bolster its conclusion. Accordingly, the court reversed the district courts' grant of motions for summary judgment and remanded for further proceedings.

The dissenting jurists complained that the majority approach "is contrary to both the Patent Act and to the Supreme Court's longstanding precedent that 'if there is no direct infringement of a patent there can be no contributory infringement.'" They contended that "Congress removed joint-actor patent infringement liability from the discretion of the courts" in 1952, thus "clearing away the morass of multi-actor infringement theories that were the unpredictable creature of common law."

Commentators have noted that the ruling strengthens patent rights by allowing liability when a patent is performed by multiple unrelated parties. Critics argue that the ruling has blazed a new trail and is likely to be brought before the U.S. Supreme Court. They suggest that indirect infringement can now be found without an act of direct infringement. The majority did place some limitations on the concept, holding that "inducement gives rise to liability only if the inducement leads to actual infringement" and that the accused inducer must "act with knowledge that the induced acts constitute patent infringement." *See Law360*, August 31, 2012.

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ISSUE 42 | SEPTEMBER 20, 2012

NEWS BYTES

The Food and Drug Administration makes available additional draft and revised draft product-specific bioequivalence (BE) recommendations on the design of BE studies to support abbreviated new drug applications. Comments are requested by November 13, 2012.

The National Institutes of Health (NIH) publishes final changes to the *NIH Guidelines* addressing "biosafety considerations for research with synthetic nucleic acids" and modifying "the criteria for determining whether an experiment to introduce drug resistance into a microorganism must be reviewed by the Recombinant DNA Advisory Committee and approved by the NIH Director" as a major action. Proposed in March 2009, the changes will take effect March 5, 2013.

The U.S. Patent and Trademark Office issues a final rule "adjusting certain patent fee amounts for fiscal year 2013 to reflect fluctuations in the Consumer Price Index." The rule takes effect October 5, 2012.

The U.S. Patent and Trademark Office issues a notice of proposed rulemaking that would "set or adjust patent fees as authorized by the Leahy-Smith America Invents Act." Among other matters, the proposed fees are intended to "provide the Office with a sufficient amount of aggregate revenue to recover its aggregate cost of patent operations, while helping the Office implement a sustainable funding model, reduce the current patent application backlog, decrease patent pendency, improve patent quality, and upgrade the Office's patent business information technology capability and infrastructure." The proposal would also reduce fees for micro entities. Comments are requested by November 5, 2012.

The U.S. Patent and Trademark Office (USPTO) issues a final rule revising the rules of practice under the Leahy-Smith America Invents Act. Effective March 16, 2013, the rule creates "a new derivation proceeding to be conducted before the Patent Trial and Appeal Board." According to USPTO, the new proceeding aims "to ensure the first person to file a patent application is actually the true inventor." ■

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Shook, Hardy & Bacon attorneys are experienced at assisting biotech and life sciences clients with a variety of legal matters such as U.S. and foreign patent procurement; licensing and technology transfer; venture capital and private financing arrangements; joint venture agreements; patent portfolio management; biomedical research and development; risk assessment and management; records and information management issues and regulations; and employment matters, including confidentiality and non-compete agreements. The firm also counsels industry participants on compliance issues, ranging from recalls and antitrust matters to facility inspections, subject to FDA, SEC, FTC, and USDA regulation.

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