Shook, Hardy & Bacon L.L.P.

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BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Federal Circuit Raises Pleading Bar in False-Marking Cases

Addressing a question of first impression, the Federal Circuit Court of Appeals has found insufficient in false-marking pleadings "conclusory allegations that a defendant is a 'sophisticated company' and 'knew or should have known' that the patent expired." ***In re: BP Lubricants USA Inc.*, Misc. Docket No. 960 (Fed. Cir., decided March 15, 2011)**. So ruling, the court granted a mandamus petition directing a federal court in Illinois to dismiss a false-marking complaint with leave to amend.

The case is one of hundreds that have been filed in recent years, alleging that the defendant intended to deceive the public by falsely marking unpatented articles with an expired patent and seeking damages under the False Marking Statute. The article at issue is a motor oil product "distributed in a unique bottle design for which BP received a design patent" that purportedly expired in February 2005. According to the complaint, BP continued to mark its bottles with the patent number after that date and "knew or should have known that the patent expired," "is a sophisticated company and has experience applying for, obtaining, and litigating patents," and marked its bottles "with the patent numbers for the purpose of deceiving the public and its competitors into believing that something contained or embodied in the products is covered or protected by the expired patent." The lower court determined that this was sufficient to state an actionable claim.

The Federal Circuit first determined that the particularity requirement of Federal Rule of Civil Procedure 9(b) applies to false marking claims. Rule 9(b) requires a plaintiff to plead "with particularity circumstances constituting fraud or mistake." The court likened false-marking claims to those brought under the False Claims Act and noted that every regional circuit has applied Rule 9(b) to the latter. According to the court, "Permitting a false marking complaint to proceed without meeting the particularity requirement of Rule 9(b) would sanction discovery and adjudication for claims that do little more than speculate that the defendant engaged in more than negligent action."

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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The court then held that in the context of a claim brought under the false-marking law, "a complaint must . . . provide some objective indication to reasonably infer that the defendant was aware that the patent expired." Rejecting the relator's arguments that calling the defendant "sophisticated" was enough, that a defendant's simply making a false marking "inherently shows scienter," and that false marking is not an individualized fraud that requires identifying actual individuals who knew about the expired patent, the court noted that knowledge can be inferred in other ways. For example, a relator can "allege that the defendant sued a third party for infringement of the patent after the patent expired or made multiple revisions of the marking after expiration."

Because its application of Rule 9(b) to false-marking allegations occurred for the first time in this case, the court agreed to grant mandamus, but to allow the relator to amend the complaint to comply with the standard the court set forth in the order.

New Forum for Patent Disputes?

According to a news source, at least one major pharmaceutical company has filed a complaint before the International Trade Commission (ITC) seeking an exclusion order to block the importation of a generic version of one of its patented drugs. Legal commentators reportedly indicated that recourse to the ITC is often undertaken by companies as a "strategic counterstrike to other litigation," but this option is evidently rarely used in the pharmaceutical sector. It may not become a common strategy either, because such disputes may not meet the ITC's requirement that a product, at least in part, be made abroad. The ITC's speed in resolving patent cases may also be viewed as a potential negative from the perspective of a brand-name manufacturer seeking to extend the life of its patents. *See The Blog of Legal Times*, March 17, 2011.

Meanwhile, legal challenges to existing pharmaceutical patents are reportedly said to be "increasing with the rapidity of a centrifuge." Only 81 such lawsuits were filed in 2005, but more than 230 were filed in 2010. Most of the challengers are generic drug makers, that, if successful, become the exclusive provider of the generic version of the drug for six months. According to a news source, a winning generic firm can take over as much as 65 percent of the branded drug's market in the first two months. Thus, a $2 million investment in litigation can return some $60 million in additional revenue during the ensuing six-month period. With a 70-percent success rate, the litigation explosion is easy to understand. Ultimately, the question raised by this pharmaceutical patent tug of war is whether government regulations have failed to correctly balance the goals of fostering innovation and preserving competition in the business. *See CNNMoney.com*, March 11, 2011.

NEW BIO BUSINESS VENTURES

Japanese Pharmaceutical Enters Partnership Focusing on Cancer Therapeutics

Japanese pharmaceutical company Eisai has reportedly entered into a $200-million worldwide partnership with a Massachusetts-based biotechnology company to "discover, develop and commercialize therapeutics targeting EZH2, an epigenetic enzyme, for the treatment of lymphoma and other cancers in genetically-defined patients."

Effective April 1, 2011, the agreement specifies that Eisai will provide the biotech company with an upfront payment, pay for "research, development and sales milestones in accordance with project progress," and also pay royalties. Eisai will also cover all costs of research and development "through human proof of concept," while the Cambridge company has the "right to opt into a co-commercialization arrangement in the United States." *See Mass High Tech,* March 10, 2011; *Eisai News Release,* March 11, 2011.

University of Massachusetts, UK Collaborate on Stem Cell Project

The University of Massachusetts Human Stem Cell Bank and Registry and the United Kingdom Stem Cell Bank have reportedly agreed to collaborate on best practices for stem cell banking, including delivery of stem cell lines for clinical use, and may explore funding opportunities for joint research projects. Providing stem cell lines to researchers working on new therapeutic treatments for degenerative illnesses, such as Parkinson's disease or diabetes, the banks plan to establish standards for stem cell line characterization, production and distribution, and will facilitate training events for stem cell researchers worldwide.

"By working closely together we have every reason to hope that we will be able to realize the full potential of stem cell research and bring breakthroughs to the clinic more quickly," Rob Buckle of UK's Neurosciences and Mental Health at the Medical Research Council told a news source. *See BioNews,* March 21, 2011.

INVESTOR NEWS

Algae-Based Biofuel Company Files $100 Million Initial Public Offering

San Francisco-based Solazyme, Inc. has reportedly filed a $100 million initial public offering (IPO) in a move that makes it one of the first biofuel companies using algae to list on a major stock exchange. Using a genetically modified strain of algae that feeds on sugar during fermentation, Solazyme produces oils and biomaterials for biofuel production and for products including clean fuels, chemicals, cosmetics, and food. The company is also reportedly

collaborating to develop its algal oils for next-generation, bio-based dielectric insulating fluids for transformers and other electrical applications, and jet fuel. *See Reuters,* March 15, 2011.

Oklahoma City Biotechnology Company Secures $22.5-Million Equity Investment

Oklahoma City-based Cytovance Biologics has reportedly received a $22.5-million equity investment to expand its biologic manufacturing capabilities. Announcing the investment by Great Point Partners of Greenwich, Connecticut, Cytovance said the capital will enable the company to fund facility, service and personnel expansion. In a separate transaction, Cytovance also apparently acquired analytical and bioprocess equipment that formerly belonged to Genzyme Corp.

"Great Point's investment allows us to accelerate our next phase of growth," said Cytovance's Darren Head. The company specializes in the production of therapeutic proteins and monoclonal antibodies from mammalian and microbial cell cultures. It claims to be a full-service contract manufacturer of mammalian and microbial biologics for biotech and pharmaceutical companies. *See Cytovance Press Release,* March 15, 2011.

Massachusetts Life Sciences Center Earmarks $25 Million for Economic Development Projects

The Massachusetts Life Sciences Center has reportedly earmarked $25 million for "high-potential economic development projects that promise to make a significant contribution to the state's life sciences ecosystem." With an application deadline of April 29, 2011, the program is part of the state's 10-year, $1 billion life sciences initiative designed to create jobs. Details of the program can be found on the center's **Website**.

In a related development, Massachusetts Governor Deval Patrick (D) recently signed an agreement with Israel to collaborate on research and development opportunities in life sciences and clean and alternative energy research. "Today, we take a new step that will ensure our mutual prosperity and leverage the talents of our uniquely skilled workforces," Patrick said. *See MassDevice; Governor Deval Patrick Press Release*, March 10, 2011.

BUSINESS CLIMATE

Gene Sequencing Is King in Scientific Research and Biotech Startups

Academic interest in gene sequencing is reportedly leading growth in scientific research disciplines, and the technology is apparently driving biotech investment. A key indicator of the surging interest in genetics is the sale of gene sequencing machines which can evidently sequence an entire human genome in less than a day for under $3,000. While discoveries have yet to translate into new medical treatments, the promise for drug development, genetic engineering in agriculture and identifying the source of food contaminants is reportedly fueling investment in genomics startups. A recent survey of the top scientific researchers apparently determined that seven of the top 10 are working in the genetics field. They are hoping that the information gleaned from genomics will bring high financial returns. *See Reuters*, March 10, 2011; *Bloomberg Businessweek*, March 17, 2011.

U.S. Biotech Clusters Face Challenges and Opportunities

Genetic Engineering & Biotechnology News has published a two-part perspective on the top U.S. biotechnology hubs, exploring how they have weathered the recession and their goals for expansion. The top two biotech clusters are located near San Francisco, San Diego and Boston/Cambridge. Job losses have reportedly amounted to 2 percent of the biotech workforce at the height of the recession in California; top needs identified by industry analysts are workforce training, loosening red tape, curtailing efforts to increase taxes, and turning around a decline in venture capital funding.

Similar challenges face the biotech industry in Massachusetts, where financing in the fourth quarter of 2010 was 40 percent lower than the fourth quarter of the previous year, although the number of deals and total financing for the year overall finished higher in 2010. Tax incentives provided by the Massachusetts Life Sciences Center, which oversees the state's $1 billion biotech initiative, have apparently not met with universal success in terms of promised job creation, and some companies had to return unused money. Still, at least a dozen companies that received tax credits exceeded their promises by creating more jobs than anticipated and significantly expanding their operations.

The second article in the series focuses on North Carolina and Maryland, which rank third and fourth as U.S. biotech hubs. Both states reportedly understand that growth depends on financing and are considering creating new funds to assist life sciences startups. Cuts in state budgets, however, have reduced available funds for an industry sector that can boast gains in employment. Biotech and pharmaceutical companies are reportedly continuing to expand in North Carolina, although gaps in early-stage and later-stage

funding as well as a shortage of executives with commercial life science experience could hamper growth. The industry is apparently working with area academic institutions to educate the next generation of business leaders.

In Maryland, the biotech industry reportedly fared well in the governor's most recent budget proposal, with stem cell research targeted to receive $12.4 million in grants, $8 million in investor tax credits planned, and just a 1 percent cut in funding to the Maryland Biotechnology Center. Governor Martin O'Malley (D) has proposed that insurance companies doing business in the state pay $99.4 million as part of an "Invest Maryland" program; in return they would receive $142 million in tax credits. The insurance money would help replenish the Maryland Venture Fund or be placed with venture capital firms that also invest in biotech companies. Invest Maryland proponents are apparently hoping that the state will recoup the losses with new taxes and business activity from biotech startups. *See Genetic Engineering & Biotechnology News*, March 7 and 8, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Judiciary Subcommittee Hearing Focuses on Patent Law

The U.S. House of Representatives Judiciary Subcommittee on Intellectual Property, Competition and the Internet has held a hearing focused on recent patent-law decisions in the courts. The March 10, 2011, hearing came in the wake of the Senate's recent approval of the America Invents Act, the first major overhaul of the U.S. patent system in more than 50 years.

Those testifying included law professors Dan Burk of the University of California, Irvine, and Dennis Crouch of the University of Missouri School of Law. Contending that patent reform is "nearing a turning point," Crouch noted that the courts have assumed a more active role in shaping patent policy. He identified elements of prior patent reform measures that were addressed by the courts and those that have not and are ripe for legislation. The latter include (i) "Easing the USPTO's [U.S. Patent & Trademark Office's] ability to set fees for its services and to retain all fees collected"; (ii) "Moving from a 'first-to-invent' system to a 'first-to-file' system"; (iii) "Expanding prior-user rights"; (iv) "Requiring that all patent applications be published by the USPTO"; (v) "Allowing pre-issuance protests (or prior art submissions) by third parties"; (vii) "Eliminating the 'best mode' requirement"; (vi) "Expanding the scope of post-grant reexamination or adding an additional post-grant opposition proceeding"; and (viii) "Easing the rules for assignee submission of patent filings without the inventor's express permission."

Burk referred to patent reform as "an ongoing, dynamic process" and called for flexible legislation to allow the process to work. According to Burk, flexibility allows the courts to address "new economic and technological situations as

they arise." He concluded, "Recent judicial decisions addressing the issues driving patent reform demonstrate that this process is working as it should."

NSF Biological Sciences Advisory Committee to Meet

The National Science Foundation (NSF) has **announced** a meeting of the Biological Sciences (BIO) Advisory Committee. Agenda items for the March 29-30, 2011, meeting in Arlington, Virginia, include the NSF and BIO 2012 fiscal year budget request, the 2010 America Competes Act, and a "progress report on BIO's ongoing experiments in innovation." The committee will also address "'information exchange environments' and STEM [science, technology, engineering, and mathematics] education, workforce and careers in science." *See Federal Register,* March 9, 2011.

Advisory Committee on Biotechnology and 21st Century Agriculture Seeks Members

The U.S. Secretary of Agriculture is requesting **nominations** for members to the Advisory Committee on Biotechnology and 21st Century Agriculture. Nominations for one- to two-year terms are requested by April 18, 2011. Members are selected to "achieve a balanced representation of viewpoints" to address USDA biotechnology policy issues. Issues of most immediate concern involve providing practical suggestions "on ways to strengthen coexistence among different agricultural crop production methods."

Committee members must be knowledgeable in one or more of these areas: (i) "recombinant-DNA (rDNA) research and applications using plants"; (ii) "rDNA research and applications using animals"; (iii) "rDNA research and applications using microbes"; (iv) "food science"; (v) "silviculture and related forest science"; (vi) "fisheries science"; (vii) "ecology"; (viii) "veterinary medicine"; (ix) "the broad range of farming or agricultural practices"; (x) "weed science"; (xi) "entomology"; (xii) "nematology"; (xiii) "plant pathology"; (xiv) "biodiversity"; (xv) "applicable laws and regulations relevant to agricultural biotechnology policy"; (xvi) "risk assessment"; (xvii) "consumer advocacy and public attitudes"; (xviii) "public health/epidemiology"; (xix) "ethics, including bioethics"; (xx) "human medicine"; (xxi) "biotechnology industry activities and structure"; (xxii) "intellectual property rights systems"; and (xxiii) "international trade." *See Federal Register,* March 18, 2011.

German Authorities Conclude Nanomaterials Cannot Be Classified as Human Carcinogens

The German Federal Institute for Risk Assessment (BfR) and the Federal Environment Agency (UBA) have reportedly concluded that while several animal studies have shown that some nanomaterials could cause cancer, scientific data are insufficient to allow these materials to be classified as

human carcinogens. While noting that further research is recommended on the issue, the agencies assert that daily exposure to nanomaterials was cause for concern.

BfR and UBA maintain that although animal research has shown that some nanomaterials, such as carbon nanotubes and titanium dioxide, may be carcinogenic when inhaled, those findings are not yet applicable to humans. But the agencies were quoted as saying that "despite existing uncertainties, findings on the carcinogenic potential of some nanomaterials should be taken seriously." *See FoodProductionDaily.com,* March 10, 2011.

LITIGATION

EU Court Finds Unified Patent Litigation System Incompatible with EU Treaties

The Court of Justice of the European Communities has determined that a draft agreement which would create a European and Community Patents Court is not compatible with existing treaties. Opinion 1/09 of the Court, March 8, 2011. According to the court, the draft agreement would give this international patent court exclusive jurisdiction, thus supplanting national courts and tribunals, and would allow the patent court to become the sole court to interpret and apply European Union law. The court issued the opinion at the request of the Council of the European Union.

The court was particularly concerned that the agreement "by conferring on an international court[,] which is outside the institutional and judicial framework of the European Union[,] an exclusive jurisdiction to hear a significant number of actions brought by individuals in the field of the Community patent and to interpret and apply European Union law in that field, would deprive courts of Member States of their powers in relation to the interpretation and application of European Union law and the Court of its powers to reply, by preliminary ruling, to questions referred by those courts and, consequently, would alter the essential character of the powers which the Treaties confer on the institutions of the European Union and on the Member States and which are indispensable to the preservation of the very nature of European Union law."

NEWS BYTES

The U.S. Patent and Trademark Office releases an Official Gazette notice outlining special accommodations for patent and trademark applicants and owners affected by the catastrophic events in Japan.

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The Food and Drug Administration is seeking comments on "the proposed extension of the collection of information concerning the guidance for industry on cooperative manufacturing arrangements for licensed biologics."

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Intellectual Property Partner Peter Strand will lead a session on communicating with jurors at DRI's Business Litigation and Intellectual Property Seminar slated for April 14-15, 2011, in Chicago, Illinois. Titled "A Thousand Words More or Less: Effectively Using Visuals at Trial," the presentation will address "the 'whys' and 'hows' of teaching and persuading jurors using the entire panoply of visual media."

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