Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

USPTO General Counsel Issues Paper on Fair Use of Non-Patent Literature in Examination Process

The Office of the General Counsel of the U.S. Patent and Trademark Office (USPTO) has released a position paper after receiving a number of inquiries about copyright infringement and the use of non-patent literature (NPL) in the patent examination process. Applicants often submit and USPTO uses NPL to demonstrate "whether an invention is novel or non-obvious in view of the prior art as of a certain date." The position paper contends that when USPTO provides unlicensed NPL to applicants or provides it on request to the public for a fee as part of the official file wrapper, "a legal document with unique significance in patent litigation proceedings," no copyright infringement has occurred because such uses constitute either fair use or transformative use under the law.

USPTO also contends that applicants submitting NPL with their applications are protected by the fair use or transformative use doctrines. Noting that most NPL submitted as part of the examination process has been "obtained through legitimate, licensed databases, and thus ha[s] already been paid for once," USPTO's general counsel finds that the copyright holder "has already been compensated for that use," a factor relevant in analyzing whether the applicant's use of the copyrighted work has harmed the market for it. Still, "[t]he USPTO takes no position on whether additional copies of NPL made during the course of patent prosecution (e.g. for the client, for other attorneys, for the inventor, or for the law firm's future reference) qualify as fair use."

NEW BIO BUSINESS VENTURES

Joint Venture to Market, License Cellulosic Bio-Ethanol

Ethanol producer POET LLC and Netherlands-based life sciences company Royal DSM N.V. have announced a 50/50 joint venture to market and license cellulosic bio-ethanol "based on their proprietary and complementary technologies." Headquartered in Sioux Falls, South Dakota, POET-DSM Advanced

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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

Biofuels LLC will produce the bio-ethanol from "corn crop residue through a biological process using enzymatic hydrolysis followed by fermentation," according to POET.

The first commercial demonstration of the technology will be at a site under construction adjacent to POET's existing Emmetsburg, Iowa, corn ethanol plant. "The initial capacity is expected to be 20 million gallons in the first year, growing to approximately 25 million gallons per year," POET said, noting that if the technology is replicated at POET's network of 26 other existing corn ethanol plants, "it could produce up to one billion gallons of cellulosic bio-ethanol per year." The joint venture's initial capital expenditure will be approximately $250 million.

"This joint venture brings together two companies leading the transition from a fossil-based economy to a bio-based economy," said POET founder and CEO Jeff Broin. "The partnership has set an ambitious goal: to make cellulosic bio-ethanol competitive with corn ethanol, which is the most competitive liquid transportation fuel on the market today." *See POET Press Release*, January 23, 2012.

INVESTOR NEWS

Washington Startup to Focus on Antibody Drug Candidates

The founders of two Seattle-based biotechnology startups have reportedly joined forces to form a company focused on creating antibody drug candidates. Theraclone Sciences founder Johnny Stine and VLST co-founder Steve Wiley have created V-Gene with initial funding of $1.2 million from an undisclosed venture investor. The funding round is expected to close before the end of March 2012.

According to a news source, V-Gene plans to develop two or three antibody drug candidates for infectious diseases and cancer, with preclinical testing to occur within the next 12 to 18 months. Once that goal is reached, a bigger venture syndicate could advance the development of the drugs with a second round of financing. Stine and Wiley reportedly opted for a smaller investment deal to keep a larger equity ownership stake in the company, which they hope to sell so they can continue discovering antibodies at the earliest stages and serving as "an antibody incubator." *See Xconomy*, January 26, 2012.

BUSINESS CLIMATE

Biotech Analysts Expect Wave of Acquisitions in 2012

Industry analysts are reportedly predicting a major wave of mergers in 2012 with four biotech deals already underway, especially where the target

companies have phase II or III drugs in the pipeline. The larger pharmaceutical companies have solid cash flows and a number of drugs coming off patent but few new ones under development; they are looking for ways to expand and strengthen their market positions. Among the possible acquisition targets, according to unnamed sources, are Idenix Pharmaceuticals, BioMarin Pharmaceuticals, Pharmacyclics, and Achillion Pharmaceuticals, which reportedly have drugs with high profitability potential in trial. A deal just announced and expected to be closed by March involves Celgene's acquisition of Avila Therapeutics, specializing in hematology drugs, for $925 million. *See CNBC.com*, January 26, 2012.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

USPTO Proposes Supplemental Examination Rules, Fees Under Patent Reform Law

The U.S. Patent and Trademark Office (USPTO) has **issued** proposed rules of practice to implement the America Invents Act requirements for supplemental examination that take effect September 12, 2012. The proposed rule would also adjust the filing fees "for filing a request for *ex parte* reexamination and to set a fee for petitions filed in *ex parte* and *inter partes* reexamination proceedings to more accurately reflect the costs of these processes." USPTO requests comments by March 26 on the paperwork burdens the proposed rulemaking is estimated to impose.

"The supplemental examination provisions will permit a patent owner to request supplemental examination of a patent by the USPTO to consider, reconsider, or correct information believed to be relevant to the patent," said USPTO Director David Kappos. "These provisions could assist the patent owner in addressing certain challenges to the enforceability of the patent during litigation" and may reduce the number and costs of inequitable conduct claims in infringement litigation.

Under the proposal, the fee for processing and treating a request for supplemental examination will be $5,180. After three months, if USPTO determines that the information provided raises substantial questions of patentability and calls for an *ex parte* reexamination, the cost will be $16,120. Filing a request for an *ex parte* reexamination will increase from $2,520 to $17,750, and the fee for filing a petition in either an *ex parte* or *inter parte* reexamination will be $1,930.

Among other matters, the proposed rule would require that a request for supplemental examination of a patent be filed by the patent owner. Each request could be accompanied by no more than 10 items of information, and if this limit is insufficient, additional requests for supplemental examination of the same patent may be filed.

The request would have to include (i) "an identification of the patent for which supplemental examination is requested"; (ii) "a list of each item of information and its publication date, if applicable"; (iii) "a list identifying any other prior or concurrent post patent Office proceedings involving the patent to be examined"; (iv) "an identification of each issue raised by each item of information"; (v) "a separate, detailed explanation for each identified issue"; (vi) "an explanation of how each item of information is relevant to each aspect of the patent to be examined and of how each item of information raises each identified issue"; (vii) "a copy of each item of information"; and (viii) "a summary of the relevant portions of any submitted document, other than the request, that is over 50 pages in length."

Failure to include any of the content requirements could result in USPTO's refusal to grant a filing date. USPTO would be required to make a determination within three months following the filing date as to "whether a substantial new question of patentability affecting any claim of the patent is raised by the items of information presented and identified in the request."

USPTO is soliciting comments on (i) "whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility"; (ii) "the accuracy of the agency's estimate of the burden"; (iii) "the quality, utility, and clarity of the information to be collected"; and (4) "the burden of collecting the information on those who are to respond, including by using appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology." *See USPTO Press Release* and *Federal Register,* January 25, 2012.

FDA Reopens Comment Period for Proposed Rule on Prescription Drug Ads to Assess "Distraction Study"

The Food and Drug Administration (FDA) has **reopened** the comment period for a proposed rule that would establish standards for direct-to-consumer (DTC) TV and radio advertisements relating to side effects of prescription drugs for humans. Proposed in March 2010, the rule would require "the major statement" in such DTC advertising to be "presented in a clear, conspicuous, and neutral manner."

FDA reopened the comment period to assess a document it added to the docket, a "distraction study" that investigates factors which may influence consumers' understanding of a drug's risks as portrayed in DTC television advertising. Titled "Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Television Advertisements," the study examined the (i) "presence or absence of superimposed text," (ii) "emotional (affective) tone of visual image" and (iii) "consistency of the visual images with the risk information."

According to FDA, the study shows that "presenting risk information at the same time in text and in audio improves consumers' understanding of the risk information." The study also apparently "did not find support for the idea that consumers' understanding of the risk information is influenced by the emotional (affective) tone of visual images with the risk information on the screen during the major statement." FDA requests comments by February 27, 2012. *See Federal Register,* January 27, 2012.

EMA Issues Draft Guideline on Testing Biosimilar Drugs with Interferon Beta

The European Medicines Agency is seeking comments on a guideline that provides the "non-clinical and clinical requirements for interferon beta (IFN-β) containing medicinal products claiming to be similar to another interferon beta already marketed." The guideline apparently represents the current view of the agency's Committee for Medicinal Products for Human Use on requirements for demonstrating the comparability of two medicinal products containing recombinant IFN-β; it must be read in conjunction with relevant European Union directives, regulations and guidelines.

Among other matters, in assessing the biosimilarity of these products, which are used to treat multiple sclerosis, *in vivo* studies in animals would not be required, "pharmacokinetic properties of the biosimilar and reference products should be compared in a crossover study for the route of administration applied for," and healthy volunteers would be considered "an appropriate study population." In addition, "[s]imilar clinical efficacy between the biosimilar and reference product should be demonstrated in an adequately powered, randomised, parallel group equivalence clinical trial, preferably double blind." Other parameters for clinical trials are set forth in the proposed guideline, and comments are requested by May 31, 2012.

LITIGATION

NRDC Challenges EPA Grant of Conditional Registration for Nanosilver Pesticide

The Natural Resources Defense Council (NRDC) has filed a petition in the Ninth Circuit Court of Appeals seeking review of a U.S. Environmental Protection Agency (EPA) order granting a conditional registration for a nanosilver antimicrobial pesticide used in clothing, baby blankets, bed sheets, and other textiles. *NRDC v. EPA*, No. n/a (9th Cir., filed January 26, 2012).

According to the environmental action group, EPA has thus allowed the sale of nanosilver to proceed for the next four years while the manufacturer "generates the required data on toxicity to human health and aquatic organisms." An NRDC spokesperson said, "EPA gave this company a four-year free pass to sell an inadequately tested product. EPA's approval of nanosilver is just

the most recent example in a long line of decisions that treats humans and the environment as guinea pigs for these untested pesticides."

NRDC filed the petition under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), challenging an EPA decision announced on December 1, 2011. It has also apparently submitted comments to the public docket calling the agency's action "illegal, irresponsible, and potentially dangerous to the public." NRDC contends that the company seeking to register its product under FIFRA is obligated to submit some safety and environmental data as part of the initial application and not after it is approved for marketing. The group warns that other manufacturers are using nanosilver in products such as food storage containers and hair dryers without government review and approval and cautions consumers to "think twice before you purchase any products with germ-fighting or antimicrobial claims." *See NRDC Press Release* and *Switchboard*, January 26, 2012.

NEWS BYTES

The U.S. Patent and Trademark Office **announces** two Patent Public Advisory Committee hearings to consider adjustments to patent fees under the America Invents Act. The February 15, 2012, hearing will be held in Alexandria, Virginia, and the February 23 hearing will be held in Sunnyvale, California. The proposed fee schedule will be made available no later than February 7, and comments are requested by February 29.

The U.S. Patent and Trademark Office **schedules** two public hearings to gather information for a report to Congress under the America Invents Act about "independent second opinion genetic diagnostic testing and its relationship to medical care and medical practice, the rights of innovators, and considerations relevant to medical costs and insurance coverage." The February 16, 2012, hearing will be held in Alexandria, Virginia, and the March 9 hearing will be held in San Diego, California. Comments are requested no later than March 26.

The Food and Drug Administration **announces** a February 28-29, 2012, meeting of the Vaccines and Related Biological Products Advisory Committee in Silver Springs, Maryland,. The committee provides advice and recommendations to FDA on regulatory issues.

The Food and Drug Administration **issues** industry guidance clarifying "requirements for product name placement, size, prominence, and frequency in promotional labeling and advertising for prescription human and animal drugs and biological products." According to the **guidance**, "disclosure of the product name in promotional labeling and advertising for these products is important for their proper identification to ensure their safe and effective use."

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The European Medicines Agency issues for public consultation a concept paper on pharmacogenomics in the evaluation of authorized medicines. Comments are requested by March 15, 2012.

UPCOMING CONFERENCES & SEMINARS

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

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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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