Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

U.S. Patent Reform Cloture Vote on Senate Agenda in September

A cloture vote on the House version of patent reform (H.R. 1249) will apparently face U.S. senators on September 6, 2011, after they return to Washington, D.C., from their summer break. The cloture mechanism, which requires 60 votes for approval, would allow the Senate to bring debate over the bill to a swift close, although it remains unclear whether any amendments will be allowed. The Senate passed its own version of patent reform legislation (S. 23), which differs to some extent from the House proposal, particularly in how the U.S. Patent and Trademark Office would handle the fees it collects. *See BNA Life Sciences Law & Industry Report*, August 12, 2011.

In a related development, generic drug industry interests are reportedly concerned about a House bill amendment that would redefine the deadline for filing a patent extension. It was purportedly introduced primarily on behalf of a Massachusetts pharmaceutical company that missed a filing deadline some 10 years ago and has been trying to correct its oversight ever since. A generics industry spokesperson reportedly said, "If enacted, it would make the deadline for filing a patent term extension essentially meaningless, and treat patentees differently than anyone else to whom statutory deadlines apply. And all to benefit one company that, by choice, waited until the last minute to file a simple form that hundreds of other companies have timely filed since 1984." *See The Hill*, August 6, 2011.

Violations of Discovery Orders Result in Default Judgment, Monetary Sanctions, Potential Discipline

A federal court in Texas has imposed severe sanctions in a patent infringement lawsuit, due to repeated violations of its discovery orders and the creation of a fraudulent discovery-related document; a default judgment has been entered against the violator, and information about the document has been forwarded to alert the district's chief judge "of the need to potentially take disciplinary measures" against counsel. *FURminator, Inc. v. PetVac Group, LLC*, No. 08-338 (U.S. Dist. Ct., E.D. Tex., Marshall Div., decided August 5, 2011). The court has scheduled a hearing for August 23 to address the amount of

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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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fees and expenses to be awarded "relating to [the plaintiff's] effort of proving-up the fraudulent email."

FURminator, which specializes in pet grooming tools and shedding solutions, sued PetVac in 2008, alleging patent infringement. PetVac delayed answering the complaint and sought additional time "in order to complete a Re-Examination of the Plaintiff's patent by the USPTO." According to the plaintiff, no such re-examination was then pending. PetVac filed an answer and counterclaims only after FURminator filed a motion for a default judgment. Because PetVac was finally represented by counsel and had filed an answer, the court denied FURminator's motion and later denied FURminator's motion to strike the answer and counterclaims. The court then entered a discovery order following a status conference at which PetVac's counsel failed to appear. FURminator subsequently filed a motion to strike the pleadings, because PetVac failed to comply with the discovery order. PetVac was given more time to comply with the discovery order and again failed to do so, leading FURminator to file another motion to strike the pleadings. PetVac responded by attaching an e-mail indicating that it had contacted FURminator on June 15, 2010, regarding PetVac's production of documents.

FURminator submitted evidence indicating that its counsel did not receive the e-mail and argued that "facial irregularities . . . might indicate it was fraudulent." The court asked for additional evidence relating to the e-mail and gave FURminator the opportunity to examine the computer of PetVac's counsel to determine whether it contained evidence about the June 15 e-mail. PetVac's counsel then reported that his computer had been stolen. FURminator subpoenaed Google, Inc. to obtain transmission logs for the lawyer's account; the logs showed that no e-mail had been sent to FURminator's counsel from defense counsel's e-mail address on that date.

The court found sufficient evidence that the defendant and its counsel had willfully violated the court's discovery orders and that the June 15 e-mail was fraudulent, thus granting FURminator's motion to strike and entering a default judgment against PetVac. In addition to determining what monetary sanctions are appropriate, the court will consider whether a permanent injunction should issue against PetVac during the August 23 hearing.

SHB Lawyer Recognized for Chinese Patent Expertise

Shook, Hardy & Bacon Intellectual Property Attorney **Thomas Moga** has been recognized as a preeminent practitioner with expertise in Chinese patents in the Legal Media Group's *Guide to Leading Practitioners: China*. Scheduled for publication in September 2011, the guide is a "one-stop reference" for Chinese and international in-house counsel; it identifies "the leading legal experts both inside and outside of PRC with expertise in Chinese business and law."

NEW BIO BUSINESS VENTURES

International Biotechs Form Joint Venture in Malaysia to Produce Animal Feed

South Korea's CJ Cheil-Jedang Corp. (CJ) and France's Arkema SA have reportedly announced a joint venture under the name CJ Arkema to develop an animal feed plant in Malaysia. Both companies will hold equal stakes in the $667 million (2 billion ringgit) investment over a 10-year period.

Expected to be in operation at the end of 2013, the plant will produce bio-methionine, a sulphur amino acid that is apparently widely used for animal feed in Asia. "This project will be a significant economic boost to the region and . . . will further stimulate the growth of the industrial biotechnology sector," Malaysian Prime Minister Najib Razak said, noting that the enterprise will produce 20 billion ringgit of sales by 2020 and create 500 jobs. *See AFP* and *Arkema Press Release,* August 12, 2011; *AsianScientist,* August 14, 2011.

Russian Firms Create Biotech Joint Venture to Develop Innovative Therapies

Russian biotechnology, pharmaceutical and investment companies have reportedly collaborated to establish a $113-million joint venture that will develop new medical therapeutics.. Started by Russia's largest biotechnology firm, the Human Stem Cells Institute (HSCI), the SynBio project's lead R&D partners are the United Kingdom's Lipoxen and Germany's Symbio Tec GmbH, which during the course of the project will merge into Lipoxen.

According to SynBio, the project will focus on developing drugs based on three technological platforms: (i) cell therapies to treat liver cirrhosis, (ii) drugs based on the recombinant human Histone H1 gene to treat cancer and other diseases, and (iii) "sustained-release drugs containing polysialic acid—[b]iobetters for the treatment of diabetes," and Alzheimer's, chronic kidney and other diseases.

HSCI General Director Artur Isaev stated, "for the first time a Russian company is acting as the initiator of an international M&A project in the biotech sector to serve both the Russian and global markets. The aim of this project is to bring to market a number of innovative drugs that will represent real progress in the treatment of socially significant diseases. Furthermore, our project is an excellent example of how the government's program for innovative development of the Russian pharmaceutical sector can be implemented." *See SynBio Press Release*, August 4, 2011; *Pharma Times,* August 9, 2011.

Array BioPharma Signs Oncology Agreement with Genentech

Array BioPharma has reportedly signed an agreement with Genentech, a member of Roche Holding AG, to develop cancer compounds involving each company's small-molecule Checkpoint kinase 1 (ChK-1) program. Under the

agreement, which includes Genentech's compound RG7602 and Array's AARY-575, Array will receive "an upfront payment of $28 million and is eligible to receive clinical and milestone payments up to $685 million and up to double-digit royalties on sales of any resulting drugs," according to an Array press release. Genetech assumes responsibility for clinical development and marketing initiatives.

Array describes ChK-1 as "a protein kinase that regulates the tumor cell's response to DNA damage," a desirable chemotherapy outcome. Drugs that inhibit ChK-1 during chemotherapy can enhance tumor cell death by interfering with their recovery from that damage. "Combining both companies' programs will maximize our chances for success in developing and commercializing this novel cancer therapy," Array's CEO Robert Conway said. "We believe ChK-1 inhibition is a key strategy for enhancing the efficacy of chemotherapeutic and other agents in cancer patients." *See Reuters* and *Array BioPharma Press Release*, August 8, 2011.

INVESTOR NEWS

T2 Biosystems® Completes $23-Million Series D Financing for Diagnostic Technology

T2 Biosystems® has closed a $23-million series D financing to support progress toward regulatory approval for its T2MR medical diagnostic technology, designed to rapidly detect *Candida,* a fungal pathogen known to cause blood-stream infections and sepsis. Led by new investor Aisling Capital, LLC, the financing round garnered additional support from existing investors Flagship Ventures, Polaris Venture Partners, Flybridge Capital Partners, Physic Ventures, Partners Healthcare, Arcus Ventures, RA Capital, Camros Capital, and WS Investments.

According to T2 Biosystems®, the company is pushing its T2MR technology through clinical trials and expects to submit it for Food and Drug Administration approval in the second half of 2012. "The T2MR technology is a direct detection diagnostic method that eliminates the need for sample purification and growth of blood cultures and provides sensitive and rapid results in less than two hours, compared to current standards that require one or more days," the company said. T2 Biosystems also plans to use the new funding to develop additional diagnostic tests for sepsis, infectious disease, therapeutic drug monitoring, and coagulation. *See T2 Biosystems Press Release,* August 10, 2011.

Proteon Lands $15 Million in New Financing Round for Kidney Disease Therapeutic

Based in Waltham, Massachusetts, with research facilities in Kansas City, Missouri, Proteon Therapeutics Inc. has reportedly drawn a new $15.2-million financing round. The company's lead product, PRT-201, is in a Phase 2 clinical study; the drug is aimed at helping chronic kidney disease patients "undergoing surgery for arteriovenous fistula creation in preparation for hemodialysis," according to the company's Website.

U.S. Securities and Exchange Commission records apparently show that the biopharmaceutical's latest round was backed by 19 firms, which were not listed by name, in an exchange of equity and options. According to a news source, previous investors include Bessemer Venture Partners, Devon Park Bioventures, MPM Bio IV NVS Strategic Fund LP, Vectis Healthcare & Life Sciences Fund, TVM Capital, Skyline Ventures, Prism VentureWorks, Intersouth Partners, and several "angel" investors. *See Mass High Tech,* August 12, 2011.

Takeda Gives Affymax® $10-Million Milestone Payment in Anemia Drug Enterprise

California-based Affymax, Inc. has received a $10-million milestone payment from Japan-based Takeda Pharmaceutical Co. to develop and market peginesatide, an investigational drug for the treatment of anemia in chronic renal-failure patients. The news comes after the Food and Drug Administration accepted Affymax's new drug application for peginesatide, formerly known as Hematide ™. If approved, the companies plan to market the drug in the United States, with Takeda commercializing the drug in other countries. *See Affymax® Press Release,* August 10, 2011.

Hopen Life Science Ventures' Second Fund Reaches $25 Million

Hopen Life Science Ventures, based in Grand Rapids, Michigan, has announced an initial close of $25 million for its second fund, which will remain open to new limited partners to raise a total of $50 million by January 2012. The life science venture capital fund expects to invest in eight to 12 companies that focus on drug, medical device, diagnostic, or related technologies.

According to Managing Director Mark Olesnavage, Hopen has already invested in four life science companies from Fund II. "Similar in focus to our first fund, Fund II will target early-stage life science companies with remarkable innovations that lead to improved health care outcomes and/or reduced health care systems costs," Olesnavage said. "We primarily focus on companies in the Midwest, pragmatically leveraging the firm's existing local, regional, national and global life science resource network to support our portfolio companies." *See Hopen Life Science Ventures Press Release,* August 4, 2011.

LEGISLATION AND REGULATORY DEVELOPMENTS

USPTO Seeks Commentary on "Implementation Documents" Before Patent Reform Law Is Enacted

In anticipation of the imminent passage of patent reform law, the U.S. Patent and Trademark Office (USPTO) has **posted** a number of documents that would begin the process of developing rules to implement the law, seeking public comment from stakeholders and the public. According to USPTO, the new law, when enacted, will set some deadlines for implementation that will require expeditious rulemaking proceedings. "Given this tight time frame, preliminary input . . . on implementation of the key provisions would facilitate this process even before the legislation has been enacted." The documents have been grouped under these general headings: patents, Board of Patent Appeals and Interferences, fees and budgetary issues, congressionally directed studies and reports, and miscellaneous.

FDA Personnel Comment on U.S. Biosimilars Program in *NEJM* Perspective Article

Food and Drug Administration (FDA) officials have published an **article** in the *New England Journal of Medicine* (*NEJM*) that discusses some of the issues facing the agency in establishing a regulatory framework under the Biologics Price Competition and Innovation Act of 2009 for the approval of biologic drugs that are "biosimilar" to already-approved products. Titled "Developing the Nation's Biosimilars Program," the August 4, 2011, article indicates that the agency is considering what scientific criteria will best address a key question for the U.S. biosimilars program: "how similar is similar enough when it comes to the substitution of complex biologic drug products in clinical practice?"

FDA is apparently turning to its experience with biologics and to lessons provided by the European Medicines Agency "which published general guidelines on biosimilars in 2005 and approved its first biosimilar in 2006." Citing a "totality of the evidence" approach, the article discusses the challenges it poses, how FDA will interact with biosimilar sponsors and what risk-based factors must be considered. The authors also address the new law's "interchangeability" standard, under which "[a] biologic will be considered interchangeable with a reference product if the developer demonstrates that it can be expected to produce the same clinical result in any given patient and that the risk associated with alternating or switching between the two products is not greater than that involved in continuing to use the reference product." Pharmacists can substitute interchangeable biologics without a presciber's intervention.

India Issues Draft Guidelines on Clinical Trial and Data Submission Requirements for New Drug Approval

The Central Drugs Standard Control Organization (CDSCO) of India's Ministry of Health and Family Welfare has issued **draft guidelines** on the clinical trial and data submission requirements that drug makers must meet before new drugs can be manufactured, marketed or imported into India. Comments are requested by August 24, 2011. While the guidelines would not, apparently, apply to biologicals and vaccines, they would be applicable to active pharmaceutical ingredients.

According to CDSCO, the guidelines are intended to assist the industry in submitting "the required documents in a more realistic manner, which in turn will also help [agency reviewers] to review such application in a systematic manner. It is apparent that this structured application with comprehensive and rational contents will help the CDSCO to review and take necessary actions in a better way and would also ease the preparation of electronic submissions, which may happen in the near future at CDSCO." *See BNA Life Sciences Law & Industry Report,* August 12, 2011.

LITIGATION

Environmental Interests Seek to Halt GE Crop Cultivation in Wildlife Refuges

Three environmental advocacy organizations have sued the U.S. Fish and Wildlife Service (FWS), contending that the agency has permitted farmers to cultivate genetically engineered (GE) crops on national wildlife refuge land in violation of the National Environmental Policy Act, National Wildlife Refuge System Administration Act and Administrative Procedure Act. *Ctr. for Food Safety v. Salazar*, No. 11-01457 (U.S. Dist. Ct., D.D.C., filed August 11, 2011). The plaintiffs seek a declaration to this effect and a permanent injunction barring FWS from "allowing any cultivation of GE crops on wildlife refuges" until the agency prepares an environmental impact statement for each of 25 refuges in eight states.

According to the complaint, FWS supported its decision to enter cooperative farming agreements with private parties, some of whom grow GE crops, with "a six-page Environmental Assessment (EA) and . . . a Finding of No Significant Impact (FONSI), despite evidence that growing GE crops on refuge lands is a major federal action which significantly impacts the quality of the human environment, is highly controversial, and which has potentially harmful effects on human health, the environment, and wildlife." The plaintiffs allege, among other matters, that their members are harmed due to interference with their aesthetic enjoyment of wildlife refuges, risk of exposure to increased herbicide use, and difficulties in growing and consuming non-GE crops due to contamination from GE crops on nearby refuge lands.

Claiming that GE crops have been growing on wildlife refuges in southeastern U.S. states since 2006 and currently encompass 69 percent of refuge agricultural lands on more than 44,000 acres, the plaintiffs allege that FWS's decision to adopt a FONSI on the basis of a cursory regional EA, was arbitrary and capricious and was undertaken "without providing proper opportunity for public notice and comment." According to a news source, an FWS spokesperson indicated that the U.S. Department of Agriculture and Environmental Protection Agency approved the GE crop plantings. *See Tennessean.com*, August 12, 2011.

NEWS BYTES

The Food and Drug Administration (FDA) requests comments on a **draft guidance document** titled "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Review." When finalized, the guidance is "intended to provide greater clarity on FDA's decisionmaking process." Comments are requested by November 14, 2011.

The Food and Drug Administration (FDA) issues **draft guidance** titled "Design Considerations for Pivotal Clinical Investigations for Medical Devices." Developed for industry, clinical investigators and agency staff, the document, when finalized, will "provide guidance to those involved in designing clinical studies intended to support premarket submissions for medical devices and for FDA staff who review those submissions." Comments are requested by November 14, 2011.

The U.S. Department of Agriculture schedules a **public meeting** of the Advisory Committee on Biotechnology and 21st Century Agriculture on August 30-31, 2011, in Washington, D.C. Topics will include practical approaches to bolster coexistence among different agricultural production methods.

The Food and Drug Administration announces the availability of **guidance** titled "E16 Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions." The guidance intends to "create a harmonized recommended structure for biomarker qualification applications that will foster consistency of applications across regions and facilitate discussions with and among regulatory authorities."

The Food and Drug Administration seeks public participation in a September 15, 2011, **meeting** in Silver Springs, Maryland, to consider the recommendations proposed in the Institute of Medicine's report, "Medical Devices and the Public's Health, the FDA 510(k) Clearance Process at 35 Years." The agency requests written public comments on the report's recommendations by September 30, 2011.

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UPCOMING CONFERENCES AND SEMINARS

The American Conference Institute will conduct a program, "Life Sciences Business Development & Acquisitions in Emerging Markets," scheduled for September 26-27, 2011, in New York City. Industry leaders will "share their recent hands-on experience in the evolving transactional environment," including developing business in "high-performing emerging countries."

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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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