Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

LAW FIRM NEWS

Garretson Provides Commentary on *Gunn v. Minton* for *Law360*

Shook, Hardy & Bacon Intellectual Property Partner **John Garretson** was quoted in a recent *Law360* article focusing on a case just argued before the U.S. Supreme Court, asking when a legal malpractice case arising from a patent dispute belongs in federal and not state court. According to Garretson, the issue boils down to whether patent law and patent lawyers are special. Because legal malpractice in most other areas of law is within the jurisdiction of state courts, the U.S. Supreme Court will have to decide whether the congressional decision to give federal courts jurisdiction over patent law "reaches so far as to have state law causes of action that require resolutions of patent issues heard in federal court," Garretson said. *Gunn v. Minton*, No. 11-1118 (U.S., argued January 16, 2013). Further details about the case appear in Issues **44** and **47** of this *Bulletin*. *See Law360*, January 11, 2013.

IP NEWS

President Signs AIA Technical Amendment Legislation

President Barack Obama (D) has signed into law **H.R. 6621**, which makes certain technical corrections to the Leahy-Smith America Invents Act. It takes effect from the date of signing—January 14, 2013. Additional details about the new law appear in Issue **48** of this *Bulletin*. Among other matters, the bill imposes an immediate bar "on using an accused infringer's failure to obtain the advice of counsel to prove that any infringement was willful or induced" in any civil action filed after the date of enactment and revises the filing deadline for *inter partes* review. *See White House Press Secretary Statement*, January 14, 2013.

Patent Trial Awards Soared in 2012, Many Reversed on Appeal

While some verdicts in patent infringement lawsuits in recent years have exceeded $1 billion, and at least seven topped $100 million in 2012, the highest verdicts have reportedly been the most volatile, with courts reversing 11 of 25 in the last year. Rutgers School of Law Professor Michael Carrier

attributes the rising verdicts to the higher dollar amounts at stake, and he noted, "Patents are more frequently being enforced." He also attributed the higher verdicts to a 2006 U.S. Supreme Court ruling that gave trial judges increased discretion to reject injunctive relief. Previously, patent owners purportedly forced high-dollar settlements because defendants faced being shut down if they lost at trial. Now, with courts increasingly reluctant to order the use of infringing products to cease, defendants are more willing to fight infringement claims at trial, while patent owners seek high damage awards from juries. *See Bloomberg*, January 18, 2013.

INVESTOR NEWS

Versartis Completes $25 Million Financing Round to Support Endocrine Disorder Therapies

California-based biotechnology company Versartis, Inc. has reportedly completed a $25 million Series C financing round led by new investor Aisling Capital. The proceeds will apparently be used to fund pediatric clinical trials of lead product VRS-317® for growth hormone deficiency in pre-pubertal children. Versartis CEO Jeffrey Cleland said in this regard, "With this substantial funding we are able to continue our comprehensive development program for VRS-317, including obtaining proof-of-concept efficacy results and preparing for the launch of a Phase 3 trial in 2014." The company focuses on developing therapeutics to treat endocrine disorders. *See Versartis, Inc. Press Release*, January 15, 2013.

Cancer Therapeutics Company Expects Public Stock Offering to Raise $50 Million

Aveo Pharmaceuticals, Inc. was reportedly planning to close a public stock offering on January 23, 2013, that would raise net proceeds in excess of $50 million that will be used to communicate with physicians about a drug the company expects to launch in mid 2014. The Cambridge, Massachusetts-based company submitted a new drug application to the U.S. Food and Drug Administration for tivozanib late in 2012, said a news source. Intended to be used in patients with advanced renal cell carcinoma, the drug is designed to optimize vascular endothelial growth factor blockage "while minimizing off-target toxicities." The company is also evaluating the drug's use for colorectal and breast cancer patients. *See Boston Business Journal*, January 17, 2013; *AVEO Pharmaceuticals, Inc. News Release*, January 22, 1013.

USDA Invests $25 Million in Bioenergy Research

According to Agriculture Secretary Tom Vilsack, the U.S. Department of Agriculture (USDA) has selected four projects that will receive a total of $25 million to research and develop "next-generation renewable energy and high-value biobased products from a variety of biomass sources." Among the

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For additional information on SHB's Life Sciences and Biotechnology capabilities, please contact

John Garretson
Intellectual Property
816-559-2539
jgarretson@shb.com

Patrick Henderson
Corporate Transactions
816-559-2115
phenderson@shb.com

Chris Johnson
Life Sciences & Biotechnology
415-544-1900
cjohnson@shb.com

Madeleine McDonough
Pharmaceutical & Medical Device
202-783-8400
mmcdonough@shb.com

Thomas Moga
Intellectual Property
202-639-5622
tmoga@shb.com

If you have questions about this issue of the Report, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

research institutions that will receive the grants is Cerametec, Inc., a Salt Lake City, Utah-based company that is working to convert "lignocellulosic biomass to infrastructure-compatible renewable diesel, biolubricants, animal feed and biopower." The company also apparently intends to develop new hybrids of energy sorghum as well as other biomass resources including switch grass and forestry residues.

The funds have been made available under the 2008 Farm Bill, and Vilsack has apparently expressed concerns about the failure of Congress to pass a new five-year farm bill. During the annual meeting of the American Farm Bureau Federation, Vilsack reportedly said that the future of biofuels is tied to the bill's passage. "I've seen the ability to use corncobs and switch grass and algae and a wide variety of things that are grown and raised or could be produced in rural areas, converted into plastics, into chemicals, into fabrics, into fibers, into fuel, into energy," he said. "It is an unlimited future. But we require support and assistance and help and a commitment through a five-year bill." *See USDA News Release*, January 11, 2013; *DomesticFuel.com*, January 15, 2013.

BUSINESS CLIMATE

Biotech Investments Rise in Q4 2012, but Remain Off for the Year

Pricewatershouse Coopers LLP has released its fourth quarter (Q4) and final 2012 venture capital investment reports and notes that "Biotechnology investment dollars declined 15 percent with volume flat in 2012 to $4.1 billion going into 466 deals, placing it as the second largest investment sector for the year in terms of dollars and deals." Q4 investments in this sector increased 3 percent over Q3 in dollars and 13 percent in the number of deals. Medical device investments reportedly increased 32 percent in dollars and 9 percent in deals from Q3 to Q4 2012. According to the company's MoneyTree™ Report, biotech and medical devices combined accounted for one-fourth of all venture capital dollars invested in 2012. Most of the 2012 declines in these sectors apparently occurred in first-time financings, with the lowest number of these deals since 1995. *See Pricewatershouse Coopers LLP News Release*, January 18, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FTC Issues Report on "Pay-for-Delay" Agreements

The U.S. Federal Trade Commission (FTC) has **published** an overview of fiscal year 2012 agreements resolving "patent disputes between a brand and a generic" prescription drug. According to the commission, of the 140 agreements filed during this period, 40 potentially involve "pay-for-delay" deals in

which "brand-name companies have paid generic firms to settle their patent challenges and, in turn, delay generic entry by 17 months longer, on average, than those that do not include some form of payment." FTC claims that delays in the market entry of cheaper generic drugs cost Americans $3.5 billion annually and add to the federal deficit, noting "The Congressional Budget Office has estimated that legislation restricting these agreements would reduce the debt by almost $5 billion over the next decade." *See FTC Press Release*, January 17, 2013.

NIH Institute Removes Some Data from Public View; Genetic Database Privacy a Concern

A study published in *Science* has reportedly shown that public databases containing genetic data could contain sufficient information to confirm the identity of a study participant. In response to the research, the U.S. National Institute of General Medical Sciences, part of the National Institutes of Health, has apparently barred public access to some data. While geneticists question the response, according to a news source, they acknowledged that genetic privacy is a concern.

Led by human geneticist Yaniv Erlich, the *Science* study team apparently used a cross-referencing technique to discover the identities of five men whose genomes were released as part of the 1,000 Genome project and had also participated in a Mormon-family project. The team, which did not release the men's names, was further able to identify their male and female relatives. According to Erlich, researchers should ensure that those participating in genome research understand that their identities may be discovered. *See Nature*, January 17, 2013.

States Consider Bills to Allow Biosimilar Substitution for Brand-Name Biologics

In the absence of U.S. Food and Drug Administration (FDA) rules providing a pathway of approval for biosimilar drugs, legislators in several states have introduced measures that would apparently allow interchangeable biosimilar substitution under certain conditions. Such bills have reportedly been introduced in Illinois, Indiana, North Dakota, Texas, and Virginia, and a Pennsylvania state senator plans to introduce one during the current legislative session. A Virginia General Assembly committee has evidently approved a bill (**H.B. 1422**) that would allow a pharmacist in the state to dispense "a biosimilar that has been licensed by the U.S. Food and Drug Administration as interchangeable with the prescribed product" with some exceptions. Given the reliance in these measures on FDA approval, it is uncertain whether, if adopted, they would have any practical effect until federal rules are finalized. *See Pharmalot.com*, January 18, 2013.

Drug Launch Within Six Months of Controller General Approval Now Required in India

According to a news source, the Drugs Controller General of India (CG) has announced that pharmaceutical companies failing to launch their drugs within six months of approval could lose their manufacturing licenses. Government safety officials are apparently concerned that some manufacturers, seeking to bypass post-marketing surveillance rules that require periodic safety reporting for new drugs, have delayed launch and introduce their drugs to the market four years after approval when they are no longer considered new drugs and reporting is not required. In a letter, the CG stated, "It has been decided in the public interest that in case an applicant/manufacturer fails to launch the product for marketing in the country within a period of six months from obtaining the permission or license, the permission/license will be treated as cancelled." *See Business Standard*, January 22, 2013.

LITIGATION

U.S. Supreme Court Refuses to Consider Patent Dispute over Vascular Grafts

The U.S. Supreme Court has denied the petition for review filed by W.L. Gore & Associates, Inc. in a dispute over the patent for a prosthetic vascular graft, thus leaving intact a $185-million jury verdict that, with interest, royalties and fees, could now be in excess of $900 million, according to C.R. Bard, Inc. *W.L. Gore & Assoc., Inc. v. C.R. Bard, Inc.*, No. 12-458 (U.S., cert. denied January 14, 2013). Additional details about the infringement litigation appear in Issues 30, 37 and 45 of this *Bulletin*. According to a news source, the parties continue to dispute the size of the award before a federal district court in Arizona. *See Bloomberg*, January 14, 2013.

Court Rejects Attempt to Keep Settled Infringement Suit Alive Through Appeal

The Federal Circuit Court of Appeals has dismissed as moot the appeal of a patent infringement dispute between parties that had settled the claims under an agreement that provided for a $50,000 reduction of the defendant's required payment if it were to succeed on any of the appealed issues. ***Allflex USA, Inc. v. Avid Identification Sys. Inc.*, No. 2011-1621 (Fed. Cir., decided January 17, 2013)**. The lawsuit involved patents relating to radio frequency identification technology used in tags to help locate lost animals or objects.

Allflex sued Avid in 2006 seeking a declaration that Avid's patents were unenforceable due to inequitable conduct and that Allflex was not liable for infringement of any of them. Avid counterclaimed, alleging infringement. The court granted summary judgment of non-infringement and granted partial summary judgment on Allflex's inequitable conduct claim, finding a genuine issue of fact as to whether Avid's president had the requisite intent to deceive the U.S. Patent and Trademark Office.

The parties then settled the claims. Avid agreed to pay Allflex $6.55 million, and the parties agreed that Avid could appeal three specific issues, as well as underlying orders and rulings. While Allflex retained the right to contest any appeal on the merits, it was barred under the agreement from disputing the existence of a live case or controversy. If Avid succeeded on appeal, Allflex would pay Avid $50,000. Avid brought the appeal, and Allflex filed no response.

The Federal Circuit ruled that the $50,000 contingent payment was not an actual damages or liquidated damages award and could not be characterized as "a reasonable estimate of a prospective damages award that would take the place of an adjudicated damages award following the appeal." In fact, the court found, it was "completely untethered to the value of any of the issues on appeal." Accordingly, the court held, "where, as here, the appellant has identified no relationship between the valuation placed on the appeal and the issues the appellant wishes to challenge, the parties have simply placed a 'side bet' on the outcome of the appeal, which is not enough to avoid a ruling of mootness."

NEWS BYTES

The U.S. Patent and Trademark Office (USPTO) **publishes** its final rule setting or adjusting patent fees under the Leahy-Smith America Invents Act. Intended to fund USPTO operations and help reduce the patent application backlog, the rule takes effect, for the most part, on March 19, 2013. Amendments to rules on (i) patent issue and public fees; (ii) fee for recording a patent assignment electronically; (iii) international application filing, processing and search fees; and (iv) international application transmittal and search fees take effect January 1, 2014.

The U.S. Patent and Trademark Office **requests** public comments "on potential practices that applicants can employ at the drafting stage of a patent application in order to facilitate examination and bring more certainty to the scope of issued patents." Comments must be submitted by March 15, 2013, and should address whether the adoption of certain practices by applicants would "assist the public in determining the scope of claims as well as the meaning of claim terms in the specification after a patent is granted."

The U.S. Food and Drug Administration **issues** a final rule on the current good manufacturing practices (CGMP) applicable to combination products. The rule, which takes effect July 22, 2013, aims "to promote the public health by clarifying which CGMP requirements apply when drugs, devices, and biological products are combined to create combination products."

The U.S. Food and Drug Administration **schedules** a public hearing "to obtain input on a potential new pathway to expedite the development of drugs,

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including biological products, for serious or life-threatening conditions that would address an unmet medical need." Registration for the February 4-5, 2013, hearing closed January 22, but comments will be accepted until March 1.

The U.S. Food and Drug Administration (FDA) **issues** a publication "containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards)." The list will help manufacturers that "elect to declare conformity with consensus standards to meet certain requirements for medical devices."

The U.S. Food and Drug Administration **announces** "the rate for the generic drug active pharmaceutical ingredient (API) and finished dosage form (FDF) facilities user fees for fiscal year (FY) 2013." The domestic API facility fee is $26,258, and the foreign API facility fee is $41,458; the domestic FDF facility fee is $175,389, and the foreign FDF facility fee is $190,389.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400

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