Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

FTC Reports "Pay-for-Delay" Deal Trend Continuing

The Federal Trade Commission (FTC) has found that the ongoing trend of drug companies settling claims filed by rival generic manufacturers with "pay-for-delay" deals is proceeding unabated. The agency's Bureau of Competition examined "156 final resolutions of patent disputes between a brand and a generic" during fiscal year (FY) 2011 and found "record numbers" resolving the litigation before a final court ruling on the merits and "significant numbers of such settlements potentially involving pay-for-delay."

According to the report, "[i]n fiscal years 2010 and 2011, the FTC received 59 potential pay-for-delay settlement agreements, almost equal to the total number of potential pay-for-delay agreements identified in the preceding six years combined." The 28 settlements logged in FY 2011 involved 25 different name-brand products with combined annual U.S. sales exceeding $9 billion.

FTC Chair Jon Leibowitz contends that the trend is keeping the cost of drugs high. He reportedly said, "While a lot of companies don't engage in pay-for-delay settlements, the ones that do increase prescription drug costs for consumers and the government each year." Meanwhile, Senators Herb Kohl (D-Wis.) and Charles Grassley (R-Iowa) have asked the "Super Committee" that is considering ways to reduce the federal budget deficit to include a previously introduced bill (S. 27) that would make these types of deals illegal. The Congressional Budget Office has apparently concluded that the bill would save the federal government some $2.68 billion over 10 years. *See The Blog of LegalTimes*, October 25, 2011.

NEW BIO BUSINESS VENTURES

ViroPharma to Acquire Swedish Pharma in Deal Worth up to $164.6 Million

Pennsylvania-based ViroPharma Inc. has reportedly signed a deal to acquire Swedish company DuoCort Pharma AB to expand its orphan disease commercial product pipeline. DuoCort has been developing the drug Plenadren® to

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treat adrenal insufficiency in adults. Once the drug is approved, ViroPharma plans to make an upfront closing cost of $33.6 million for DuoCort, with potential additional milestone payments of up to $131 million.

According to ViroPharma, Plenadren® is a once-daily medication designed to more closely mimic the body's natural secretion pattern of cortisol for patients who have adrenal insufficiency and depend on such therapies as exogenous glucocorticoid replacement. With orphan-drug designation status confirmed and 10 years of market exclusivity, the company anticipates the commercial launch of the drug in the European Union in approximately one year and estimates sales of up to $50 million in peak years.

"This acquisition is consistent with ViroPharma's objective of broadening our orphan drug portfolio of therapies for patients with serious conditions who lack effective treatment options," said ViroPharma Chief Executive Officer Vincent Milano. "Plenadren will be an important drug for patients with Addison's disease and other chronic adrenal insufficiencies, and is the first new drug in this therapeutic area in over 50 years." *See ViroPharma Press Release*, October 27, 2011.

INVESTOR NEWS

NewLink Genetics Sets IPO Estimates

NewLink Genetics Corp., an Iowa biopharmaceutical company focusing on immunotherapeutic products for improved cancer treatment options, has reportedly established the expected range of its initial public offering (IPO) of 5.5 million shares at $10 to $12 a share. Expecting to raise about $53.4 million, the company said it hopes to use the funds to complete testing of its pancreatic cancer drug HyperAcute Pancreas, which, currently in late-stage trials, has received fast-track and orphan-drug designations from the Food and Drug Administration. The funds will also be used for other research and working capital. According to its Website, the company is involved in earlier-phase trials for lung cancer and melanoma treatments. *See Wall Street Journal,* October 26, 2011.

Biotech Secures $42 Million in Series A Funding Round for Dermatology Advances

Dermira, a private California company focused on developing and marketing new therapies in dermatology, has reportedly secured a $42-million Series A financing to support therapeutic advances. Part of the funding has been used to acquire Valocor Therapeutics, which features a product pipeline for the treatment of acne, inflammatory skin diseases and other dermatologic conditions. Investors are Bay City Capital, New Enterprise Associates and Canaan Partners.

According to Dermira, the funds will specifically be targeted to lemuteporfin, "a potent and selective topical photodynamic therapy (PDT) for acne," and "a robust pipeline of novel, topical small molecule therapeutics for sebaceous gland hyperactivity and inflammatory skin diseases." The company notes that it "will also continue to pursue additional development and commercial opportunities in dermatology for licensing or acquisition." Financial details of Dermira's Valocor buyout were not disclosed.

"Although there are currently many serious and highly prevalent skin conditions that have unsatisfactory treatment options available, dermatology has attracted limited research and investment resources towards truly innovative therapeutics," Dermira's CEO was quoted as saying. "We have assembled an outstanding combination of technology, management and investors to address this need and lead the development of new categories of dermatology products, with the potential to improve the way patients are treated." *See Dermira Press Release,* October 20, 2011.

$10-Million Prize Offered for Accurate Human Genome Sequencing

Craig Venter, creator of rapid DNA sequencing technology, has reportedly told *Scientific American* that he and two partners will award $10 million to the first team that can meet "medical grade" accuracy in human genome sequencing, a factor that has been lacking since the technology was first developed in 2000. With contributions from X-Prize Foundation, Medco Health Systems and his own Venter Institute, Venter says the prize aims to propel the preventive-medicine technology by sequencing the genomes of 100 centenarians.

"The technology is changing pretty rapidly, which is a good thing," Venter told the magazine in a question-and-answer interview. "But right now there's no technology out there that meets the standards that we've set. If genome sequencing is going to have true medical impact, it needs to get up to [a higher] diagnostic quality level. And we're a long way from that."

Although costs of the technology have decreased, accuracy has not improved, Venter said. By sequencing the genomes of people who are at least 100 years old, contestants might discover a trait common among them, such as "wellness genes that would protect you from cancer if you were genetically predisposed to getting it," Venter noted. "You're not going to get a definitive answer just by looking at 100 genomes [of ordinary people]. Centenarians [present] a more interesting group than most because it emphasizes the wellness aspect rather than the illness aspect."

The prize, he said, "becomes the truth serum for all the claims from all these companies and all these technologies. Without an independent test, there is no ability to sort out the claims, and there are some pretty wild ones out there. The hope is there will be one or several winners out there. For guys and gals working in their garages, [the $10-million prize] is a strong incentive." *See Scientific American,* October 26, 2011.

BUSINESS CLIMATE

Venture Capital Goes to Capitol Hill to Decrease Regulatory Burdens on Medical Device Industry

According to a recent *New York Times* business article, venture capital funds are contributing to the campaigns of politicians calling for streamlined Food and Drug Administration (FDA) medical device approval procedures and increasing their lobbying presence in Washington, D.C. This activity is partially attributed to the need for congressional reauthorization of the law that requires medical device makers to pay fees to FDA, giving lawmakers their first opportunity to amend the agency's procedures since 2007.

With a spate of new regulatory reform bills specifically targeting medical device regulation pending before the House and Senate, a legislative battle is apparently brewing. In 2011, House committees have conducted a number of hearings focusing on FDA medical device procedures, with most of the witnesses representing investors, entrepreneurs, industry consultants, trade group officials, or patients claiming that agency delays had harmed them or a family member.

House Democrats have reportedly expressed concerns about imbalanced testimony, suggesting that the hearings, by excluding witnesses injured by purportedly flawed devices, have failed to consider potential dangers "if medical devices are not appropriately regulated." Industry supporters contend that FDA approval delays are caused by personnel turnover, an unwieldy bureaucracy and top officials who have overreacted to recent problems with medical devices by becoming risk-averse. One industry analyst noted that investors are particularly concerned with the speed of approval because this begins a process of start-up acquisition in which early investors, who may not be as concerned about patient experience with a device, profit by cashing out. *See The New York Times,* October 25, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FDA to Reassess Bar Code Technologies for Drugs and Biological Products

The Food and Drug Administration (FDA) is **seeking** comments on its plan to reassess bar code technologies for drugs and biological products. FDA requests comments by January 9, 2012, with reply comments by February 23.

According to FDA, the "Bar Code Final Rule" of 2004 requires a bar code on certain human drug products and biological products. The agency plans to reassess the costs and benefits of the rule and to identify any relevant changes in technology that have occurred since it took effect. "This is an opportunity for interested persons to share information, research, and ideas

on the need, maturity, and acceptability of alternative identification technologies for the identification, including the unique identification, of drugs and biological products," states the agency. "FDA will use the information received to assess whether the Bar Code Final Rule is achieving its intended benefits as effectively as possible or should be modified."

FDA specifically invites small businesses to address such topics as (i) any successes or challenges in adopting linear bar code technologies, (ii) product coding changes since 2004, and (iii) unplanned expenses if an alternative to the linear bar code were implemented. *See Federal Register,* October 26, 2011.

USPTO and National Science Foundation Establish Small Business Pilot Program

The U.S. Patent and Trademark Office (USPTO) and National Science Foundation are collaborating to establish a pilot program that will provide small business innovation research (SBIR) awardees "with comprehensive intellectual property support through the agency's small business programs and resources." USPTO will offer monthly Webinars covering an array of intellectual property (IP) topics and is also providing its IP awareness assessment tool to small business awardees. SBIR is a competitive, awards-based program "that enables small businesses to explore their technological potential and provides the incentive to profit from its commercialization."

The October 2011 program launch coincides with a presidential memorandum directing all federal agencies with research facilities "to improve the transfer of research from their labs to the marketplace." According to USPTO Director David Kappos, "For many small, innovative companies, the ability to grow, hire new employees, and compete effectively in the global marketplace hinges upon securing patent and trademark protection. Patents have become increasingly vital to securing the financing and investment needed to build and scale businesses." *See USPTO Press Release*, October 28, 2011.

ASTM International Approval of Renewable Jet Fuels Leads to Commercial Trials

After ASTM International approved the commercial use of biofuels for aviation, several carriers reportedly began commercial trials, mixing the renewable jet fuels, made from natural plant oils and animal fat, with conventional kerosene. Additional information about ASTM International's action appears in Issue 15 of this *Bulletin*.

Lufthansa and KLM Royal Dutch Airlines have apparently begun using the fuels, and other airlines expect to do so. Still, carrier officials indicate that the trials mark the beginning of alternative fuel use, with regular future use dependent on policy decisions about environmental and social issues. While alternative fuels reportedly reduce carbon dioxide emissions and their use has not led to delays or unexpected aircraft behavior, some have questioned biofuels' impact on farm commodity prices and land use. *See The New York Times*, October 25, 2011.

LITIGATION

Drug Maker Brings First Amendment Challenge to Off-Label Use Rules

Par Pharmaceutical, Inc. has filed a declaratory judgment action against the U.S. Food and Drug Administration (FDA) in a District of Columbia federal court, seeking an order barring the agency from enforcing regulations that criminalize off-label drug promotions on the ground that they violate First Amendment free speech rights. ***Par Pharm., Inc. v. United States*, No. 11-01820 (U.S. Dist. Ct., D.D.C., filed October 14, 2011)**.

According to the New Jersey-based generic and branded drug maker, FDA regulations pertaining to unapproved (off-label) uses of approved drugs place manufacturers in a Catch-22 situation: "changing the drug's labeling to add directions for the off-label use violates the [Food, Drug, and Cosmetic] Act's criminal 'new drug' rule, but based on the government's view of the FDA's 'intended use' regulations, *not* changing the labeling to add those directions violates the Act's 'misbranding rule.' The manufacturer's truthful speech about on-label use of its drug thus violates at least one of these criminal provisions."

Noting that the Act "does not limit or interfere with the authority of health-care professionals to prescribe or administer any FDA-approved drug to any patient to treat any condition or disease" and that off-label uses are "widespread, medically accepted and government-subsidized," the complaint contends, "it is critical that healthcare professionals have access to accurate, comprehensive, and current information concerning off-label uses."

The complaint specifically addresses the company's prescription drug Megace® *ES*, an appetite-stimulant hormone. According to Par Pharmaceutical, while FDA has approved the drug for AIDS-related wasting, the medical community "widely views" it "as one of the most effective treatments for wasting in geriatric and cancer patients." The company is allegedly unable to conduct placebo-controlled clinical studies for this use because physicians contend that administering a placebo "would be contrary to the best interests of the patients, in light of [the drug's] accepted off-label use." Without such testing, the company cannot apply to the FDA for a new drug use to change the product's labels and promotional materials and thus cannot market it for this widely approved use.

The company seeks a declaration that FDA's interpretation of the "intended use" regulations "violate[s] the First Amendment as applied to Par's truthful and non-misleading speech to healthcare professionals concerning on-label use of its approved drug in settings where the drug is prescribed for off-label use, and enjoining defendants from enforcing the regulations to prohibit Par's speech."

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NEWS BYTES

The Food and Drug Administration (FDA) **announces** a November 8-9, 2011, meeting in Jefferson, Arizona, of the Science Advisory Board to the National Center for Toxicological Research (NCTR). The November 8 session will be open to the public and will focus on scientific initiatives and accomplishments during the past year.

The U.S. Patent and Trademark Office and European Patent Office launch a dedicated **Website** for the Cooperative Patent Classification initiative, aimed at helping patent examiners "efficiently conduct thorough patent searches."

The U.S. Patent and Trademark Office (USPTO) hosted a Webinar on October 31, 2011, to provide senior agency officials the opportunity to discuss the America Invents Act. The speakers outlined USPTO implementation plans and answered submitted questions.

The National Cancer Institute **initiates** a public/private industry partnership "to promote translational research and development opportunities of nanotechnology-based cancer solutions." A consortium of government, pharmaceutical and biotechnology companies will "evaluate promising nanotechnology platforms and facilitate their successful translation from academic research to clinical environment." Eligible companies interested in participating must contact the National Institutes of Health.

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