Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Obama Signs Patent Reform Bill into Law; Implementation Requires Funding

Patent reforms became law in the United States on September 16, 2011, when President Barack Obama (D) signed the bipartisan Leahy-Smith America Invents Act, saying it would allow patent applications to be processed three times faster and help jump-start job growth in America. Without additional funds, however, the U.S. Patent and Trademark Office (USPTO) will be unable to fully implement the legislation when major provisions take effect next year.

According to USPTO Director David Kappos, unless Congress approves an "anomaly" to the continuing budget resolution, the office will "be going on a starvation diet." The anomaly, usually used to make technical corrections to a resolution that continues spending at current levels, would allow USPTO to meet the new law's tight deadlines by allowing it to keep the user fees it receives. At a minimum, H.R. 1249 requires USPTO to hire 1,500-2,000 examiners and 100 administrative law judges.

USPTO has issued several documents providing guidance on the law's requirements, including a table of effective dates and a new fee schedule. Other significant changes include moving from a first-to-invent to a first-to-file system and modifications to and creation of procedures for challenging patent applications and issued patents at the USPTO, thus bypassing costly litigation over patents that should not have been granted. *See National Journal*, September 16, 2011; *BNA U.S. Law Week*, September 20, 2011.

NEW BIO BUSINESS VENTURES

Russia Invests in British Drug Company Using Nanotech in Pharma Products

RusNano, a Russian state corporation formed to advance nanotechnology, has invested £300 million for a 40 percent stake in a new British drug company, Pro Bono Bio™, that will use the proceeds of European drug sales to provide free or reduced-price pharmaceuticals to third world countries. The Anglo-Russian project, developed by Celtic Pharma Holdings in London, has already reportedly launched its first prescription drug, a nanotechnology-based pain

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treatment for osteoarthritis. Additional product launches are anticipated in coming months involving treatments for inflammatory skin disorders such as psoriasis and eczema.

Pro Bono Bio™ CEO John Mayo, who founded Celtic, said that the company would "deliver attractive shareholder returns while at the same time making a growing contribution to healthcare budgets in areas such as the East African Community where resources are extremely limited." *See Pro Bono Bio™ News Release*, September 12, 2011.

INVESTOR NEWS

Biofuel Producer Seeks $100 Million in Initial Public Offering

New Hampshire cellulosic ethanol producer Mascoma Corp. has reportedly filed a form with the U.S. Securities and Exchange Commission about its proposed initial public offering (IPO) of common stock shares. According to news sources, the company hopes to raise $100 million through the IPO to further develop its production process, which involves creating enzymes from genetically modified yeast and bacteria to break down plant sugars and convert them into ethanol. By combining enzymatic digestion with fermentation, the process is apparently less expensive than other manufacturing methods. The new funding would also be used to expand the company's marketing and to build manufacturing plants that would convert wood into ethanol. *See Bloomberg*, September 16, 2011; *Mascoma Corp. Press Release*, September 19, 2011.

New Investments to Support Hepatitis C Drug Development

Drug-discovery startup Cocrystal Discovery, Inc. has reportedly closed a deal with Israel-based Teva Pharmaceutical Industries Ltd. that could be worth up to $45 million. Teva's initial $7.5 million investment will be used to advance research and development for antiviral drug candidates targeting the Hepatitis C virus. Cocrystal's platform apparently combines high-resolution X-ray crystallography with advanced computational methods to discover and develop small molecule inhibitors of the viral replication complex. The company is also focusing on treatments for influenza and the rhinovirus. Teva's investment could lead to a 23 percent share of Cocrystal. *See Cocrystal Discovery, Inc. Letters to Shareholders*, September 19, 2011.

Meanwhile, Teva recently announced that it would invest $19 million in Cure Tech Ltd. and provide financing of up to $50 million for the company's research and development initiatives. The latest investment will reportedly give Teva a 75 percent share in the Israeli biotech, which is working on treatments for large B cell lymphoma and metastatic colorectal cancer. Cure Tech's lead drug is described as "a humanized monoclonal antibody directed against PD-1, a B7 family-associated protein." *See Associated Press*, September 13, 2011.

Company Secures $10 Million in Venture Capital Financing to Improve DNA-Sequencing Technology

NABsys, Inc., a Rhode Island-based developer of electronic systems used for sequencing and analyzing single-molecule DNA, has reportedly raised $10 million in new venture capital funding, closing a Series C preferred stock financing round. Since 2009, the company has raised more than $21 million to support continuing development and commercialization of its solid-state technology and innovations in chemistry and algorithms to improve DNA sequencing accuracy, speed and cost. According to the company, performance enhancements will affect biological research in many fields. *See NABsys Inc. Press Release*, September 14, 2011.

$15 Million Raised in Series A Funding Round for Leukemia and Cancer Treatments

Tensha Therapeutics, Inc., which is developing small molecule bromodomain inhibitors to treat cancer and other conditions by regulating disease-associated gene transcription, has apparently raised $15 million in Series A financing through its sole investor, HealthCare Ventures. Based on technology developed and licensed to Tensha by the Dana-Farber Cancer Institute, bromodomains are protein modules that can block the activity of aberrant proteins responsible for midline carcinoma, acute myeloid leukemias, multiple myeloma, and other malignancies.

According to institute researcher James Bradner, "This financing will allow Tensha to advance our first-in-class program through clinical proof-of-concept, lay the groundwork for clinical studies in other cancer indications, and advance the preclinical development of bromodomain inhibitors in areas outside of oncology," including inflammatory and metabolic disorders. *See Tensha Therpeutics, Inc. Press Release*, September 12, 2011.

Private Investors Bring $4.5 Million to Nanotech Cancer Drug Delivery Research

According to a news release, Aura Biosciences, Inc. has raised an additional $4.5 million from unnamed private investors to continue developing nano-enabled drug delivery systems. The Cambridge, Massachusetts-based biotech will use the funding to advance its research programs to the clinic. Current data reportedly suggest that the company's NanoSmart™ platform can detect cancers and distant metastases earlier and provide "precisely targeted" treatment. Founder and CEO Elisabet de los Pinos said, "The development of a real-time detection system that is sensitive and specific for epithelial tumors, and that can further enable a targeted treatment to distant metastases, could lead to major improvements in efficacy and survival rates." *See Aura Biosciences, Inc. News Release*, September 8, 2011.

BUSINESS CLIMATE

Biopharma M&A Activity Increases in First Half of 2011

A new report by a Swiss-based manager of health care-focused investing concludes that mergers and acquisitions among North American and European pharmaceutical and biotechnology companies increased in the first half of 2011, with transaction values reaching $51.6 billion. Exits apparently brought good returns to venture investors: "[t]he ratio of upfront proceeds to invested capital jumped to 3.0x for venture-backed companies sold (up from a factor of 1.6x in 2010)." Given market turbulence in the weeks following the report's coverage, the authors suggest that any outlook on biopharma M&A activity could be problematic. Still, with trade sales remaining "the preferred and possibly the only exit route for the next 6-12 months" for venture and private equity investors, the authors suggest that "[c]ash-strapped companies with ongoing clinical development programs will thus face a buyers' market."

Forbes Features Entrepreneur Whose Small Startup Approach Is Key to Success

According to *Forbes*, pharmaceutical inventor K. Peter Hirth has, since the 1990s, employed an innovative business model that is leading the way to the successful development of new drugs. He launches small startups and, when their new therapies are ready for clinical trials, either licenses them to major pharmaceutical companies or sells the startup for hundreds of millions of dollars to begin another. Hirth, who enjoys getting new drugs approved, has apparently overseen the creation of drugs that treat anemia and cancer and pills that fight cancer by blocking enzymes. His "smaller-is-better" approach has reportedly won converts, and some large pharmaceutical companies are now buying small research firms and letting them function independently. Some companies are also discussing the creation of small research units or even breaking up their laboratories into smaller, outsourced groups to enhance innovation. *See Forbes*, September 26, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

GEN Magazine Considers FDA "Hints" on Biosimilar Approvals

In a September 20, 2011, Analysis & Insight article, *GEN* magazine focuses on a recent *New England Journal of Medicine* discussion by Food and Drug Administration (FDA) officials about developing an approval pathway for biosimilar pharmaceuticals.

Additional information about the FDA article appears in Issue 19 of this *Bulletin*. Noting that the agency has revealed its plan in broad strokes only, the *GEN* article discusses some of the open issues with Shook, Hardy & Bacon Life Sciences & Biotechnology Practice Co-Chair Madeleine McDonough.

According to McDonough, "early communication and collaboration" between the agency and biosimilar developers will likely be required and could involve "higher fees" to fund the product reviews that will be required. She noted, "The medical risks are going to depend on how close the biosimilar is to a reference product and what the hypothetical mechanism of action would be that could cause adverse effects or untoward effects. And I don't think you can do that with some broad brush. I think it's really going to be compound specific." Commenting on recently issued draft European guidelines on biosimilars, McDonough said, "It used to be that a lot of companies wanted to get FDA approval first because so many countries relied on FDA approval to shorten the pathway to approval in those countries. I wonder if, at least for biosimilars, that whole paradigm will be reversed and that biosimilars will be approved far later in the United States than in Europe."

The article concludes, "The draft guidance that FDA eventually releases should go far toward bringing more lower-cost biosimilars to market—one ostensible purpose of healthcare reform. How far it goes and how helpful it is to biologic drug developers will depend on how many of the blanks left by its article in *NEJM* FDA fills in over the next few weeks."

Biotechnology Interests Seek More Clarity on Safety Reviews in FDA's Draft Nanotechnology Guidance

Commenting on the Food and Drug Administration's (FDA's) "Draft Guidance for Industry on Principles for Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology," biotech industry interests asked the agency to clarify whether it intends to require "additional safety reviews or environmental or occupational safety and health assessments" by stating that some nanotech products "may merit examination." Additional information about the draft guidance appears in Issue 15 of this *Bulletin*.

The Biotechnology Industry Organization's (BIO's) comment also seeks clarity on "what counts as a product involving the application of nanotechnology, and how the Draft Guidance should be interpreted with respect to pharmaceuticals in particular." The BIO comment further calls for the guidance document to address, as "critically important to evaluation of nanotechnology based products," matters such as delivery route, particle size instrumentation, agglomerates and aggregates, and inert materials. The main theme of BIO's comment is that because nanomaterial science "has been around for decades, . . . just because a product is considered to be 'nanotechnology derived material' or 'nanosized material' should not imply potential harm or risk."

In a related development, nanotechnology researchers are currently debating whether governments should define what constitutes an engineered nanomaterial for regulatory purposes. Andrew Maynard, a former research physicist who now directs the Risk Science Center at the University of Michigan School

of Public Health, opines on his blog *2020 Science* that definitions are desired by policy makers "scrambling to use science to justify a predetermined conclusion—that engineered nanomaterials should be regulated on the basis of a hard and fast definition—rather than using science to guide their actions."

Maynard was responding to comments published in a recent issue of *Nature* by Hermann Stamm of the European Commission Joint Research Centre Institute for Health and Consumer Protection, calling for a definition for labeling and classification purposes and to decide whether safety assessments may be necessary. Stamm also apparently claimed that engineered nanomaterials are heterogeneous.

Maynard suggests that policy makers "put aside preconceptions" and instead ask "how new generations of sophisticated (or advanced) materials interact with biological systems; where these interactions have the potential to cause harm in ways not captured within current regulatory frameworks; and how these frameworks can be adapted or altered to ensure that an increasing number of unusual substances are developed and used as safely as possible—no matter what label or 'brand' is applied to them." *See 2020 Science*, September 6, 2011.

Public Advocacy Group Seeks Change in Generic Drug Labeling Rules

Public Citizen recently submitted a **citizen petition** to the Food and Drug Administration, calling on the agency to adopt rule changes that would allow generic drug makers to change their products' approved labels more expeditiously. According to the petition, "while [generics'] market shares have increased, the regulatory system has not adjusted to compel generic manufacturers to shoulder responsibility commensurate with their status as major market players," and "the rise of generics has weakened incentives for brand-name manufacturers to remain actively engaged in the market for their products after losing patent protection." Patient safety is threatened, says Public Citizen, because brand-name manufacturers do not invest resources in post-approval safety monitoring as generic market share increases, "while generic manufacturers face no concomitant increase in incentive and have no authority to update labeling."

The petition was filed in the wake of a U.S. Supreme Court determination that federal rules requiring that generic drug makers use the same information on product labels as their name-brand counterparts preempt state common-law claims failure to warn involving generics. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Public Citizen also notes that the product liability law of many states immunizes brand-name companies from liability for harm caused by inadequate labeling where the injured patient took a generic form of the drug. The advocacy organization's proposal would authorize generic drug makers to use the same procedures that brand-name manufacturers use to gain approval for updated product warnings based on new information.

FTC Report on Authorized Generic Drugs Generates Comment and Concern

The Federal Trade Commission has released a **report** titled "Authorized Generic Drugs: Short-Term Effects and Long-Term Impact," in which the agency concludes that "pay-for-delay" agreements between name-brand drug manufacturers and generic drug makers is "a practice that causes substantial consumer harm" by keeping drug prices high. Responses to the report were swift, with Democratic lawmakers calling for the agency and Congress "to halt these abusive practices." Representative Henry Waxman (D-Calif.) said, "Brand-name drug companies use anticompetitive agreements to keep prices high and overcharge consumers," while Senator Jay Rockefeller (D-W.Va.) noted, "This report proves what I have long suspected: that promotion of authorized generics can reduce the incentive for true generic companies to enter the market. That allows brand name companies to unfairly dominate the marketplace long after their patents have expired."

The Generic Pharmaceutical Association (GPhA) countered that the report is misleading to consumers. According to Bob Billings, the association's executive director, "By continuing to push its misguided policy to ban pro-consumer patent litigation settlements, the FTC is gambling with consumers' savings." Billings pointed to research conducted by RBC Capital Markets purportedly suggesting that "had a ban on patent litigation settlements been in place over the past 10 years, up to 100 of the approximately 280 first-time generics launched between 2000 through 2009 would have been delayed until the expiration of the brand patent."

Billings also said, "It's the patent, not the patent settlements that holds up the launch of a generic drug. Patent settlements have never prevented competition beyond the patent expiry, and generally have resulted in making lower-cost generics available months and even years before patents have expired." *See GPhA Press Release* and *Zecco: Market News Story*, August 31, 2011.

European Nations Sign MOU to Manage Life-Science Information

Denmark, Finland, the Netherlands, Sweden, and the United Kingdom have reportedly signed a memorandum of understanding (MOU) with the European Molecular Biology Laboratory to create an infrastructure that would both manage and safeguard life-science data generated by publicly funded research. Referred to as ELIXIR [European Life-science Infrastructure for Biological Information], the initiative is intended to support life-science research by making biological information, such as genes, proteins and complex networks, freely available to academic and industry researchers. Hoping to add additional countries to the MOU, ELIXIR coordinator Janet Thornton indicated that actual implementation and construction of the infrastructure will launch in November 2011. *See ELIXIR Press Release*, September 7, 2011; *GenomeWeb Daily News*, September 13, 2011.

LITIGATION

Myriad Litigants Seek Rehearing, Stalling Case Before Federal Circuit Panel

Court watchers were reportedly surprised that both sides to litigation involving the patentability of genetic discoveries filed petitions for a rehearing before the divided Federal Circuit Court of Appeals panel that issued a ruling on the matter in July 2011. Observers apparently expected that the parties would instead file for consideration by the full Federal Circuit court or request that the U.S. Supreme Court consider hearing an appeal. Additional information about the case, *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, No. 2010-1406, appears in Issue 18 of this *Bulletin*.

The plaintiffs, who sought to invalidate the patents, reportedly argue that the majority erred because "the language of the patents defines the function, not the structure of the patented genes and gene fragments; [and] gene fragments with the altered chemical structure identified by the Court exist in nature." Myriad Genetics Inc., the patent holder that won the appeal, sought to render the case moot, without vacating the opinion on the merits, by removing from the case the only plaintiff with standing. *See BNA Life Sciences Law & Industry Report*, September 9, 2011.

Researchers Appeal Stem Cell Funding Ruling

The scientists who were unable to stop federal funding of human embryonic stem cell research in a federal district court have reportedly filed an appeal from the adverse ruling. Details about U.S. District Judge Royce Lambreth's decision in *Sherley v. Sebelius*, No. 09-1575, appear in Issue 18 of this *Bulletin*. The scientists opposed such research and argued that it diverted money from their adult stem cell work. In July 2011, Judge Lambreth rejected their challenge to National Institutes of Health guidelines allowing federal funding of research using embryonic stem cells created since 2001 but not the research that derives the cells from human embryos. *See Reuters*, September 19, 2011.

Court Appoints Damages Expert in Patent Infringement Lawsuit

Taking an apparently unusual step, a federal court in California has reportedly appointed an expert to testify on damages in patent infringement litigation that has generated contentious hearings over the issue between Oracle America Inc. and Google Inc. According to a news source, Oracle submitted a $6.1-billion damages report in May 2011, but the court ordered its exclusion on the ground of overreaching. Defending the litigation, Google claims that the patents in suit are neither valid nor infringed and that Oracle is not entitled to damages. The court has reportedly rejected this argument as well.

The court supported its decision by stating, "Far from complicating the jury's decision on damages, as Google argues, the testimony of a Rule 706 expert

would assist the jury by providing a neutral explanation and viewpoint. This assistance will be particularly useful because both sides have taken such extreme and unreasonable positions regarding damages in this action." A legal scholar found the court's decision to appoint an expert reasonable but commented, "I think that if we start going down the road where we're going to let court-appointed fact finders testify at trial, we really are giving up some of our belief in the jury system." *See Law.com*, September 2, 2011.

European Court of Justice Weighs In on GMOs

In recent weeks, the European Court of Justice (ECJ) has issued rulings in two cases involving genetically modified organisms (GMOs). In one, the court determined that honey with trace amounts of pollen from GM corn must be labeled as such and undergo a full safety authorization before it can be sold to consumers. **Case C-442/09, *Bablock v. Bayern*, 2011 ECJ (Sept. 6, 2011)**. According to green groups, this "groundbreaking" decision could force the European Union (EU) to strengthen its already tight restrictions on GMOs.

In the second case, the ECJ specified under what directives and regulations EU member states may provisionally suspend or prohibit the sale or use of genetically modified food and feed. **Cases C-58/10 to C-68/10, *Monsanto SAS v. Ministre de l'Agriculture et de la Pêche*, 2011 ECJ (Sept. 8, 2011)**. The ruling arose from a case involving a French prohibition on the planting of MON 810 maize seeds.

While some may have concluded that the court struck down the French GMO ban, the ruling was more limited, with the ECJ indicating that member states may adopt such bans under the emergency measures clause of Regulation 1829/2003, which "requires Member States to establish, in addition to urgency, the existence of a situation which is likely to constitute a clear and serious risk to human health, animal health or the environment." The ECJ also indicated that member states wishing to adopt emergency GMO measures must comply with "the procedural conditions set out in Article 54 of Regulation No 178/2002." *See The Guardian*, September 7, 2011.

Thijs Etty, Assistant Professor of EU Law at VU University Amsterdam, noted that while the decision represents a "symbolic victory" for Monsanto and the EU Commission, "its practical impact may be more limited than might appear at first sight: with yesterday's ruling on zero tolerance for GMO pollen in bees opening up once again the coexistence debate full swing, combined with the ongoing discussions about the Commission's very flawed proposal for legislation to supposedly allow member states to ban cultivation of GMOs on their territory, . . . today's decision by the ECJ may only serve to further convince many member states that they need much stronger rules in place to allow them to ban cultivation."

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NEWS BYTES

The U.S. Patent and Trademark Office requests public comment on the burdens of maintaining utility patents for which fees must be paid periodically after the patent is granted. With a focus on reducing paperwork and respondent burden, the office directs attention to the time and financial burdens of meeting the information collection requirements of the rules for patent maintenance fees. Comments are requested by November 7, 2011.

The Food and Drug Administration announces a public conference for the pharmaceutical/biotechnology industry titled "FDA/Xavier University Global Outsourcing Conference." Scheduled for October 3-5, 2011, on the Cincinnati, Ohio, campus of Xavier University, this event will bring together FDA officials, global regulators and industry experts to address topics such as managing global complex supply chains and improving outsourced product quality.

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Intellectual Property Attorney Thomas Moga will be serving as the moderator for a panel discussion on "Protections of Biotechnology Inventions in China, US and Europe: A Comparative Perspective," during BIO China, the BIO International Convention in Shanghai, China, October 12-13, 2011. Shook, Hardy & Bacon is co-sponsoring this event, which will feature exhibits, networking opportunities and programs on patent enforcement, biosimilar innovation, clinical trials, and global trends in vaccine development. Moga's panel features Jasemine Chambers, the U.S. Patent and Trademark Office's deputy administrator for external affairs, and Chris Sappenfield, senior counsel for Ibis Biosciences, Inc., who will discuss how legislative and regulatory changes have affected biotechnology patenting in three jurisdictions.

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