Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Proposed Patent Reforms Continue to Generate Commentary; Business Method Patent, First-to-File and USPTO Fee Provisions Cause Concern

Retired Judge Paul Michel, who formerly served as chief judge of the Federal Circuit Court of Appeals and retired in 2010 to participate in the debate over patent reform, recently published a comment on a House bill (H.R. 1249) provision that would single out "business method patents" for different treatment under the law. According to Michel, section 18 of the proposed legislation would add "a special new procedure in the patent office that favors financial firms in several unjustified ways."

First, the section would require the creation of a new transitional post-grant review proceeding to review the validity of business method patents. Michel contends that this would allow "patents to be invalidated even though properly granted under the laws applicable at the time, even when they have been upheld by the courts or after re-examination in the Patent Office." The section would also apply retroactively and impose new standards on courts deciding whether to stay a civil infringement action involving a patent undergoing transitional review. Michel claims this will allow "lawsuits to be stalled for years while the patent office reviews the old patents under the new laws" and will skew "the standards courts normally apply in deciding whether to freeze ('stay') the lawsuit until the patent office completes all reviews."

Finally, Michel notes that the measure would create "an automatic right of appeal if the stay is granted, guaranteeing further delay and burdening the appeals court with reviewing trial court orders not normally appealable." He further observes, "No other industry is so protected, no other type of patent so degraded. That is not equal justice under the law, but special interest legislation at its worst. Favoritism for financial firms will encourage other industries likewise to seek legislative exemption from normal rules and equal justice. That will further fragment patent law, expanding complexity and delay just when simplicity and expedition are needed to spur recovery and create jobs." He calls for section 18 to be stripped from the bill before final passage.

When Michel testified before a subcommittee of the House Committee on the Judiciary in February 2011, he emphasized the need for reforms that

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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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would address delays and ameliorate crushing workloads at the U.S. Patent and Trademark Office (USPTO). He stated that the office needed several thousand additional examiners, dozens of additional board of appeals members and a major modernization of its IT systems. *See Patently-O*, July 7, 2011.

Shook, Hardy & Bacon Intellectual Property Of Counsel Tom Moga has also expressed concerns about the proposed reforms; he was quoted in the June 29, 2011, issue of *GEN Magazine: Genetic Engineering & Biotechnology News* as saying, "I understand the benefits of first-to-file, but I'm very concerned that now that it's a race to the patent office, the quality of our patent applications will suffer."

He also suggested that the House version, by failing to allow USPTO to keep the fees it collects, could jeopardize U.S. leadership in the biotech arena. He said, "If we don't get our biotech patent group organized and fix this, we are certainly going to fall behind in one of the areas that we've been leaders in. . . . On the one hand, you hear people in Congress grouse about our lack of competitiveness. On the other hand, they won't take the steps that are necessary to make sure our patent office has the funds it needs to keep up with the technology and provide the services that applicants need to move their applications along at a reasonable time frame."

NEW BIO BUSINESS VENTURES

Biotech Startup to Develop Protein Replacement Skin Therapy

Biotechnology startup Lotus Tissue Repair, Inc. has reportedly closed a $26 million Series A financing led by Third Rock Ventures. The new Massachusetts-based biotech company will use the financing to advance technology it has licensed from the University of Southern California for the treatment of dystrophic epidermolysis bullosa, a rare skin disease in children that causes skin blisters and can lead to squamous cell skin cancer. The proprietary recombinant collagen type VII (rC7) technology would, if successful, be the first to treat the disease, which results from mutations in the gene encoding collagen type VII. According to Lotus founding CEO Mark de Souza, "More broadly, our rC7 technology shows promise across a range of dermatologic conditions including diabetic foot ulcers, venous stasis ulcers and similar conditions where collagen type VII could help accelerate chronic wound healing." *See Lotus Tissue Inc. Press Release* and *Boston Business Journal*, June 30, 2011.

INVESTOR NEWS

Kinetic Concepts Purchased for $6.3 Billion

Kinetic Concepts, Inc., a San Antonio-based company that makes low-pressure wound technology, has reportedly been purchased by a private equity consor-

tium for $6.3 billion. The all-cash deal, if approved by regulatory authorities and shareholders, is expected to be closed in the second half of 2011; it will apparently include Kinetic debt. The company reported revenue of $2 billion in 2010. See *The New York Times*, July 13, 2011.

Sorbent Therapeutics Completes $36 Million for Cardio-Renal Treatments

California-based Sorbent Therapeutics has announced that it has expanded its Series B financing by $36 million, bringing total proceeds of the financing round to $53 million for new kidney and heart failure treatments. The private biopharmaceutical company has developed polymeric drugs that are not absorbed into the bloodstream, but can soak up and remove excess sodium and fluids present in the blood of people with failing hearts and kidneys.

"There have been no major breakthroughs in congestive heart failure or dialysis for a while, and this could be an extremely safe and effective way of managing these diseases without a systemically active drug," said Bob Nelsen, a managing director with Arch Venture Partners, an existing investor that participated in the Series B financing. Other investors include Sofinnova Ventures, CMEA Capital and AgeChem. *See Sorbent Therapeutics Press Release* and *Xconomy*, June 30, 2011.

Biotech IPOs May Reinvigorate Swiss Health-Care Industry

Analysts have reportedly been eyeing several Swiss biotechs that could help revive Switzerland's sagging health-care industry should they decide to go public. Potential Swiss initial public offering (IPO) biotech candidates include Molecular Partners, a Zurich-based biotech firm developing an experimental eye medicine; Actelion Ltd., which offers a popular lung medicine; and Pevion Biotech Ltd., which is working on HIV and malaria vaccines.

According to a news source, the Swiss health-care industry has seen just two IPOs since 2006 after setbacks in new-medicine development. Investment in Swiss biotechs reportedly fell to 255 million Swiss francs (US$304 million) in 2010, down from 370 million francs in 2009. A peak occurred in 2007 with 885 million francs invested.

"Below the surface there are really interesting second-generation companies that have a lot of potential," Jean-Philippe Tripet, a Zurich venture capital company managing partner, was quoted as saying. "They're not just one-product, pass-or-fail types of companies." *See Bloomberg,* July 7, 2011.

BUSINESS CLIMATE

Massachusetts Unveils $2 Million Life Sciences Partnership with Israel

Massachusetts Governor Deval Patrick (D) has announced a new partnership

with Israel to encourage life sciences, clean energy and technology innovation and entrepreneurship. The initiative, to be known as the Massachusetts-Israel Innovation Partnership, calls for Massachusetts to commit nearly $1 million, with Israel providing up to $1 million in matching funds. "This agreement will promote research collaborations, industrial partnerships and commercialization of new technologies, expanding opportunity and job growth both in Massachusetts and Israel," Patrick said. *See Mass. Gov. Deval Patrick Press Release,* June 29, 2011.

Report Showcases Stable Maryland Biotech Industry

Maryland Governor Martin O'Malley (D) has released a report showing that the state's life sciences sector contributed one-third of job gains between 2002 and 2010, with the industry's annual average salary climbing nearly 50 percent.

Prepared by the state's Department of Business and Economic Development, the "Maryland Life Sciences: Job Analysis and Economic Impact Report" also found that the biotech sector supported 71,600 jobs at federal agencies, higher education institutions and the private sector. Drugs and pharmaceuticals represented 20 percent of the state's life science jobs, according to the report.

"Maryland's life sciences industry continues to be one of our strongest economic drivers, creating high-paying jobs even in tough times and helping to feed, fuel and heat our planet with life-saving discoveries," said O'Malley, who created BioMaryland 2020 to unify the state's efforts to advance the biotech industry. Some Maryland economic development officials have reportedly pitched the state's experience with federal agencies as a selling point for new and existing biotechs.

In a related development, Maryland's biotech tax credits reportedly drew more than 180 applications within three minutes of a first-come, first-served opportunity for $8 million available this fiscal year. According to a news source, the Biotechnology Investment Incentive Tax Credit is refundable, giving investors cash back if the amount is larger than their taxes due to the state. *See Md. Gov. O'Malley Press Release,* June 28, 2011, and *The Baltimore Sun*, July 5 and 7, 2011.

LEGISLATION AND REGULATORY DEVELOPMENTS

Medical Product Companies Ask FDA to Clarify Policies on Off-Label Uses

Leading U.S. pharmaceutical and medical device manufacturers have filed a citizen petition with the Food and Drug Administration (FDA) calling on the agency to clarify its regulations and policies on off-label uses of drugs and

medical devices. Filed on July 5, 2011, the petition discusses the recognized value of off-label uses and notes how, while off-label use is legal, FDA has made it difficult for manufacturers to communicate off-label information because its policies on manufacturer communications are ambiguous, use undefined terms and must be pieced together from a variety of sources, including nonbinding letters and guidance.

Specifically, the petition seeks a rulemaking "embodying FDA's current policy on [manufacturer] responses to unsolicited requests [about off-label uses]." The petition also seeks "a comprehensive, binding statement as to the contours of the safe harbor" provided by a rule that otherwise prohibits a drug manufacturer from promoting an investigational new drug as safe and effective. The safe harbor allows manufacturers to engage in a "scientific exchange" about investigational new drugs so they could be made available to "desperately ill patients." The petition requests that whatever regulation is adopted on this point include medical devices.

The companies further seek clarity from FDA on their communications about off-label uses with "formulary committees, payors, and similar entities," and they request "formal FDA policies specifically relating to manufacturer dissemination of clinical guidelines that may discuss off-label uses." According to the petition, clinical guidelines are created by medical professionals, academic institutions and government agencies to provide the latest information and data concerning diagnosis, management and treatment. To the extent that such guidance recommends off-label uses, the companies seek clarification on "whether, or to what extent, a manufacturer can disseminate such guidelines."

Lawmakers Introduce Stem Cell Bill

U.S. Representatives Diana DeGette (D-Colo.) and Charlie Dent (R-Pa.) have introduced a bill (H.R. 2376) supporting embryonic stem-cell research.

The Stem Cell Research Advancement Act of 2011 would codify the National Institutes of Health (NIH) guidelines "for carrying out all human stem cell research, embryonic and adult," and would require NIH to review its guidelines at least every three years and make updates "as scientifically warranted," according to DeGette, who has championed such legislation for several years.

To address ethical concerns, the bill would mandate that "human embryonic stem cells eligible for use in research" be derived from "human embryos that have been donated from *in vitro* fertilization clinics, were created for the purposes of reproductive treatment, and were in excess of the clinical needs of the individuals seeking such treatment." It must also be shown that "the embryos to be donated would never be implanted in a woman and would otherwise be discarded." Donors would not be paid and would be required to sign a written consent form under the proposal. The legislation would also prohibit the use of federal funding for human cloning under the NIH

guidelines.

"With two human trials already underway, for the treatment of spinal cord injuries and degenerative eye diseases, it is clear ethical embryonic stem cell research is beginning to bear fruit for the millions of Americans facing debilitating diseases and conditions," DeGette said in a statement. "This legislation would place into statute a framework to ensure such critical research can be conducted unimpeded by political interference." *See U.S. Rep. Diana DeGette Press Release,* June 27, 2011.

Biotechnology Advisory Committee Members Announced

The Department of Agriculture's Office of the Under Secretary, Research, Education, and Economics has **announced** the appointment of 22 members to the Advisory Committee on Biotechnology and 21st Century Agriculture. Among those named was Gregory Jaffe, director of the Center for Science in the Public Interest's (CSPI) Biotechnology Project. CSPI is an advocacy organization that focuses on diet, nutrition and health issues.

Committee members represent the biotechnology, organic food and seed industries; farming communities; food manufacturers; state governments; consumer and community development groups; medical professionals; and academic researchers. The committee will meet up to four times a year in Washington, D.C. *See Federal Register,* June 30, 2011.

LITIGATION

Supplemental Briefs Filed in Stem Cell Funding Dispute

The parties to a dispute over whether National Institutes of Health (NIH) guidelines on stem cell research violate a congressional appropriations rider that bars federal funding for research in which a human embryo is destroyed have filed their supplemental briefs on competing motions for summary judgment pending before a U.S. district court in Washington, D.C. *Sherley v. Sebelius*, No. 09-01575 (U.S. Dist. Ct., D.D.C., briefs filed June 24, 2011). As discussed in **Issue 13** of this *Bulletin*, a divided D.C. Circuit Court of Appeals panel determined that the NIH guidelines are not clearly at odds with the statute (Dickey-Wicker) and thus, the district court abused its discretion when it granted a preliminary injunction to two scientists who opposed the guidelines and briefly halted federal funding of this research.

The plaintiffs **contend** that they are entitled to summary judgment, arguing that funding for human embryonic stem cell (hESC) research inevitably creates "a more-than-minimal risk that human embryos will be destroyed in order to derive more hESCs for federally funded research purposes." They also argue that the guidelines were promulgated in violation of the Administra-

tive Procedure Act because NIH purportedly disregarded "roughly 30,000 comments—60% of all comments received—that question the merits of hESC research based on its many ethical and scientific shortcomings."

The Justice Department **argued** on behalf of Secretary of Health and Human Services Secretary Kathleen Sebelius that the D.C. Circuit's ruling "conclusively resolves plaintiffs' claim under Dickey-Wicker," and thus "summary judgment should be awarded in favor of defendants."

The defendants' brief underlines the D.C. Circuit's distinction between hESC research, which can be funded, and research that derives hESCs, which cannot be funded under Dickey-Wicker. The brief predicted that the plaintiffs will "advance an alternative theory that Dickey-Wicker forbids any actions that 'incentivize' the destruction of embryos." In fact, the plaintiffs argued in their brief that the guidelines and research encouraged by the guidelines "obviously subject embryos to risk of injury or death because they use, and create demand for, hESCs that can be obtained only by destroying embryos."

According to the defendants, "almost all of the stem cell lines on the NIH registry were created from embryos donated prior to the Guidelines, when federal funding for research on new lines was not available." They further observe, "Plaintiffs' assertion that the Guidelines somehow create a known risk to embryos is meritless when the Guidelines do nothing to change the private sources of funding for the process of derivation. It is, accordingly, implausible to assume that a researcher 'knowingly' subjects embryos to risk simply because he uses NIH funds instead of private funds for hESC research. Given the range of options that is available to potential donors, and would be available to them with or without federal funding for hESC research, it is not plausible to read Dickey-Wicker to prohibit funding for hESC research on plaintiffs' 'incentivization' theory."

Company Sues "Patent Troll" for Declaration that Patents Are Invalid or Not Infringed

A company which has allegedly been warned that one of its Web functions violates the patents owned by Lodsys, LLC has filed a lawsuit seeking a declaration that the Lodsys patent claims are invalid or that the plaintiff has not infringed the patents. *DriveTime Auto. Group v. Lodsys, LLC*, No. n/a (U.S. Dist. Ct., D. Ariz., filed June 30, 2011).

According to DriveTime's complaint, Lodsys is a company that buys patents without any intention of manufacturing products covered by the patents. Characterizing the defendant as a "patent troll," DriveTime asserts that Lodsys acquired rights to the patents intending to "generate revenue from litigation and the threat of litigation alone." Lodsys has already allegedly filed a number of patent infringement actions against others including some that have developed iPhone® applications, and a number of defendants have brought

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declaratory judgment actions similar to DriveTime's against the company.

DriveTime asserts that it received a demand from Lodsys on June 21, 2011, alleging that DriveTime was infringing Lodsys patents and seeking to negotiate a non-litigation licensing arrangement, while reserving its rights to take legal action against DriveTime. According to the complaint, the technology at issue is DriveTime's Web Chat Functionality.

NEWS BYTES

The U.S. Patent and Trademark Office (USPTO) agrees to participate in a pilot program to test an enhanced framework for the Patent Prosecution Highway. Participating countries include Australia, Canada, Finland, Japan, Russia, Spain, and the United Kingdom.

USPTO requests comments by September 6, 2011, on its plan to review existing significant regulations in response to Executive Order 13563. USPTO's plan is included in the Department of Commerce's "Preliminary Plan for Retrospective Analysis of Existing Rules."

USPTO issues a proposed rule that would adjust "certain patent fee amounts for fiscal year 2012 to reflect fluctuations in the Consumer Price Index"; most fees would increase 2.3 percent. Comments are requested by July 27, 2011.

USPTO releases the third edition of the "Trademark Trial and Appeal Board Manual of Procedure" and requests that recommendations to improve its form or content be submitted via e-mail.

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