Shook, Hardy & Bacon L.L.P.

ISSUE 6 | JANUARY 27, 2011

BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

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IP NEWS

AFBF Asks Industry to Handle GM Crop Patent Expirations

The American Farm Bureau Federation (AFBF) has reportedly voted to amend its policy on the expiration of genetically modified (GM) crop patents, calling on industry to develop "a protocol for biotech crops before coming off patent." With patents set to expire for more than 24 GM varieties in coming years, the 6-million-member farmers' coalition has evidently asked industry to craft a plan aimed at avoiding shortages or trade disruptions. AFBF delegates at an Atlanta, Georgia, meeting apparently discussed grower and seed group concerns about whether generic seed versions will be available and accepted by other nations. "There just needs to be a way to deal with it," said AFBF Director of International Policy Rosemarie Watkins. *See Reuters,* January 13, 2011.

NEW BIO BUSINESS VENTURES

Emerging Healthcare Solutions Announces Organ Regeneration Joint Venture

Emerging Healthcare Solutions Inc. (EHSI) has announced a joint venture with its wholly owned subsidiary, Celulas Genetica, to test an organ regeneration treatment using a NASA bioreactor that EHSI is licensed to use outside the United States. Known as the "Rutherford Procedure," the treatment features proton-beam technology that destroys diseased organ tissue for regeneration using adult stem cells, according to EHSI. The bioreactor facilitates the growth of human cells, such as stem cells, with a simulated weightlessness technology, purportedly producing cell cultures of better quality than those grown in Petri dishes.

Panama-based Celulas Genetica reportedly obtained the license to develop and market the Rutherford Procedure from the Chinese firm BBFITCL. The joint venture will allow EHSI to expand its global presence by further pursuing stem cell research and testing in China. "We are very serious about developing the Rutherford Procedure into a viable treatment for liver disease," said EHSI President and Chief Executive Officer Cindy Morrissey. "Our research on the

procedure and on proton-beam centers worldwide has convinced us that China is the best place to pursue further testing and trials." *See EHSI Press Release,* January 18, 2011.

PPD Creates Joint Venture to Discover Novel Biotherapeutics

North Carolina-based PPD Inc. has reportedly announced a joint venture with Taijitu Biologics Limited to discover novel biotherapeutics. Named BioDuro Biologics, the Singapore-based joint venture, in collaboration with MAB Discovery GmbH in Munich, Germany, "expands PPD's capability to deliver unique, highly differentiated drug discovery services for biopharmaceutical companies across the globe," according to PPD.

"Developing a best-in-class, innovative technology platform for the discovery of monoclonal antibodies allows us to continue to deliver highly valued discovery services for our clients in the growing area of large molecule drug discovery," PPD's Lee Babiss said. "As PPD continues to invest in drug discovery, we are well-positioned to deliver high quality, innovative drug discovery technologies and expertise that advance our clients' compounds more quickly and cost efficiently." *See PPD Press Release*, January 10, 2011.

INVESTOR NEWS

North Carolina, China Agree to Collaborate on Bioscience Research Facility

North Carolina Governor Bev Perdue (D) has reportedly reached an agreement with Chinese officials to create a 150,000-square-foot research facility in the state's Research Triangle Park (RTP) for pharmaceutical, biotechnology and other businesses that want to expand in the United States and China. Expected to open in 2013, the biosciences gateway at RTP's Hamner Institutes for Health Sciences may expand up to 1 million square feet during the next five to seven years.

At the January 18, 2011, signing, Perdue told a delegation of Chinese politicians, investors and business leaders that North Carolina wished to learn how to "collaborate and build strong partnerships" with them. Hamner, a nonprofit founded in 1974 to study chemical safety, will apparently work with the Chinese investment firm XY Group to identify biotech opportunities for companies and universities. "This campus will be a very important gateway for Chinese companies that want to do business in North Carolina," XY Group Yunsong Yang told a news source. *See The Charlotte Observer*, January 19, 2011.

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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BUSINESS CLIMATE

WSJ Calls Personalized Medicine a Challenge for Pharmaceutical Industry

According to a *Wall Street Journal* "Heard on the Street" column, personalized medicine, which uses genetic information to target drugs to individual users, may be the latest industry buzzword, but it could pose more of a threat than an opportunity. On the upside, personalized drugs could reduce health-care costs, given that most treatments are ineffective half the time, and they could reduce the incidence of adverse reactions, resulting in fewer liability claims. Still, because the technology will likely cut into the sales of so-called block-buster drugs and have a limited market, personalized drugs could affect profit margins. Expected to benefit most from personalized medicine are diagnostic companies that can sell the tests needed to determine what formulation is needed for a specific patient. *See The Wall Street Journal Europe*, January 24, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

New Employment Regulations Prohibit Genetic Screening

U.S. Equal Employment Opportunity Commission (EEOC) rules implementing part of a federal law that makes it illegal for employers to discriminate against workers or job applicants based on their genetic information became effective January 10, 2011. The Genetic Information Nondiscrimination Act of 2008 also makes it unlawful for employers to request, require or purchase genetic information.

Prompted by concerns about the potential misuse of genetic information by insurance companies and employers, the law applies to businesses with 15 or more employees, along with labor unions, employment agencies, and apprenticeship and training programs. The law has several exemptions, such as allowing the disclosure of genetic information in response to a court order. *See Associated Press*, January 12, 2011.

House Agriculture Committee Addresses Biotech Crop Approval Process

The House Agriculture Committee conducted a public forum January 20, 2011, to discuss matters relating to the U.S. Department of Agriculture's anticipated action on the deregulation of genetically engineered (GE) alfalfa. The agency has proposed several options, including partially deregulating GE alfalfa and establishing isolation distances and geographic limits on where the crop is grown. According to Agriculture Secretary Tom Vilsack, this option "mirrors a healthy and productive conversation between GE, non-GE and organic interests that is already underway in the industry and continues to evolve."

Republican House members, including committee chair Frank Lucas (Okla.), are concerned about the "increasingly troublesome delays" in the regulatory

approval process for GE crops. Lucas also emphasized that USDA's authority over GE crops and plants does not extend to "rhetorical concerns advanced by activist groups." Because USDA determined that GE alfalfa does not pose a quantifiable plant pest risk, Lucas contended, "This should be the end of the debate. A product that has been repeatedly found to be safe should be deregulated." Lucas argued that the partial deregulation option was developed "to prevent future lawsuits," and as such "is a political objective … outside the scope of legal authority." *See House Agriculture Committee Press Release*, January 20, 2011.

Senators Join House Colleagues in Clarifying Intent of Biosimilars Law

Democratic and Republican senators have echoed their House colleagues in a **letter** to the Food and Drug Administration (FDA), indicating that Congress intended, in enacting the Biologics Price Competition and Innovation Act, that the exclusivity to be accorded innovations under its terms refers to data exclusivity and not market exclusivity for innovator products. Information about the House letter appears in **Issue 5** of this *Bulletin*.

In their January 7, 2011, letter, Senators Kay Hagan (D-N.C.), Orrin Hatch (R-Utah), Michael Enzi (R-Wyo.), and John Kerry (D-Mass.) noted that the data exclusivity provision "prohibits FDA from allowing another manufacturer of a highly similar biologic to rely on the Agency's prior findings of safety, purity and potency for the innovator product, for a limited period of time." The senators agreed with the House members that a biosimilar manufacturer is not prohibited from "developing its own data to justify FDA approval of a full biologics license application rather than an abbreviated application that relies on the prior approval of a reference product."

Patent and Trademark Office Creates Online Tools to Improve Manuals

The U.S. Patent and Trademark Office (USPTO) has created two "online discussion tools designed to solicit input from the intellectual property community." The tools will specifically be used to update and improve the Manual of Patent Examining Procedure (MPEP) and Trademark Manual of Examining Procedure (TMEP).

The tools were developed to help facilitate discussion and feedback by (i) "encouraging readers to post comments about the current text, on a section-by-section basis, to point out errors, suggest clarifications, and suggest examples of interpretations"; (ii) "posting preliminary content and encouraging the community to comment on the preliminary content before it becomes official"; (iii) "periodically summarizing and following up on the comments on each section to ensure that meritorious suggestions are acted upon while streamlining the comment process"; and (iv) "providing a forum for the community to discuss and debate topics such as how to interpret recent court decisions."

"The objective is to ensure that the MPEP and TMEP are as accurate, complete and current as possible and enable practitioners and examiners to find information easily and get accurate and complete guidance," according to USPTO's David Kappos. "This input from users will assist us to further improve these resources as well as our examining processes." *See USPTO Press Release,* January 12, 2011.

LITIGATION

Fourth Circuit Rejects Challenge to Stem Cell Research Funding; Plaintiffs Lacked Standing

The Fourth Circuit Court of Appeals has dismissed two lawsuits challenging the executive order and implementing regulations allowing the use of some frozen embryos for stem cell research. ***Doe v. Obama,*** **Nos. 10-1104 & 10-1106 (4th Cir., decided January 21, 2011)**. One set of plaintiffs sought to represent a putative class of all frozen embryos in the United States; the second set were parents who have children they adopted as frozen embryos and who were considering adopting embryos in the future. The court expressed its appreciation for the litigants' deeply held convictions, but said that courts lack the constitutional authority to hear cases where the plaintiffs lack a particularized and imminent injury fairly traceable to the defendant's challenged action.

According to the court, neither set of plaintiffs could allege particularized and imminent injury fairly traceable to the executive order and implementing regulations, and thus, they lacked standing to pursue their claims. The appeals court affirmed the lower court's ruling dismissing the claims and noted that "the complaint presents what is essentially a policy dispute over the administration's approach to stem cell research." If the court were to hear cases in such circumstances, it would be transformed "into more political organs, less differentiated from the workings of the political branches whose actions we are now requested to review."

NEWS BYTES

The U.S. Patent & Trademark Office **announces** agreements with its Australian counterpart that will extend and expand work sharing between the two agencies. Such agreements generally allow applicants to obtain patents in multiple jurisdictions more quickly.

PricewaterhouseCoopers "**2010 Patent Litigation Study**" reports that median damages awards in jury-tried cases doubled in the 2000s over a comparable period in the 1990s and are significantly higher than the median damages awarded in bench-tried disputes.

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UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Intellectual Property Of Counsel Tom Moga will discuss the relationship between genetic resource recording and the World Trade Organization's TRIPS Agreement at the American Intellectual Property Law Association's 2011 Mid-Winter Institute. Slated for February 2-5, 2011, in Orlando, Florida, the institute will feature Moga as part of its session "on the state of Section 101 eight months post-*Bilski,* including how courts are approaching subject matter patentability in both the computer/electronics and biotech industries," as well as its impact on international treaties.

Shook, Hardy & Bacon Intellectual Property Partner Peter Strand will lead a session on communicating with jurors at DRI's Business Litigation and Intellectual Property Seminar slated for April 14-15, 2011, in Chicago, Illinois. Titled "A Thousand Words More or Less: Effective Using Visuals at Trial," the presentation will address "the 'whys' and 'hows' of teaching and persuading jurors using the entire panoply of visual media." ■

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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.

SHB is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most challenging national and international product liability and mass tort litigations.