Shook, Hardy & Bacon L.L.P.

ISSUE 16 | JUNE 30, 2011

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

U.S. Patent Reforms Take Another Step Forward

With House passage of the Leahy-Smith America Invents Act (H.R. 1249), reform of U.S. patent law moved closer to enactment. Because the proposed legislation, approved in the U.S. House of Representatives on June 23, 2011, by a 304-117 vote, differs in some respects from the Senate's reform measure, the bills must be reconciled before the reforms become law. U.S. Patent & Trademark Office (USPTO) Director David Kappos applauded the House vote, claiming that the bipartisan legislative effort "will transform our patent system, enhance our Nation's competitiveness and promote economic growth and job creation."

Like the Senate version, the House bill would adopt a "first-to-file" rule that will align U.S. law with that of other countries, changing how this country grants patents, which are currently awarded to the "first to invent." Other reform provisions would establish a new process for reviewing patents after they are issued and allow third parties to provide information on other parties' patent applications. The legislation would also give inventors a grace period following public disclosure of their inventions to file for patents. Both bills would slow down the "false patent marking suits" that have created a new litigation industry by allowing only the U.S. government to file suits to recover the statutory penalty. Competitors injured by false marking could sue for damages equal to the competitive injury. Neither final bill includes provisions that would have restricted patent infringement damages.

A compromise that allowed the House bill to move to a vote will allow USPTO fees, collected in excess of its annually appropriated budget, to be held in a reserve fund for the office's sole use. The House will, however, be required to separately authorize USPTO's use of any part of the fund. This provision may undergo revision during the reconciliation process; according to the White House Office of Management and Budget, the provision does not ensure access to the reserve fund, and "[t]he administration looks forward to working with Congress to provide additional direction" that will provide "timely access to all of the fees collected." The compromise resolved concerns that allowing

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

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.

USPTO to be self-funding would prevent effective appropriations oversight. According to a news source, the American Intellectual Property Law Association, which supports the House and Senate bills, has expressed reservations about the fee compromise.

Other concerns raised during House deliberations included a potential conflict with the Genetic Nondiscrimination Act. According to Representative Louise Slaughter (D-N.Y.), the Act's sponsor, a manager's amendment to the patent reform bill could allow human genes to be patented, which would jeopardize the Act. In this regard, she reportedly said, "If I didn't already have enough complaints against this manager's amendment, I want to call attention to the House that after 13 years of work, we finally got genetic nondiscrimination passed in this Congress so that people could feel free to have genetic tests. This manager's amendment for the first time talks about the patenting of human genes. That must never, ever happen."

Some patent law practitioners and scholars oppose the proposed reforms, primarily because they would "undeniably expand the size of the federal bureaucracy and increase the cost and complexity of the American patent system." George Washington University Law School Research Professor John Duffy recently explained his opposition to the "big government reform bill" by describing the new administrative proceedings that have been added to existing procedures.

Those proceedings, if finally approved, would add to existing "patent examination," "interference," "reissue and correction," "ex parte reexamination," and "inter partes reexamination," three procedures that Duffy designates as "post-grant review," "supplemental examination" and "a special 'transitional post-grant review proceeding for review of the validity of covered business-method patents.'" According to Duffy, "Even the last three decades—which, in terms of historical precedent, have seen extraordinary inflation in bureaucratic processes at the Patent Office—are outdone by this single bill." *See The New York Times,* June 21, 2011; *The Hill*, June 22, 2011; *USPTO Press Release*, June 23, 2011; *The Wall Street Journal* and *The National Law Journal*, June 24, 2011.

NEW BIO BUSINESS VENTURES

Swiss Biopharmaceutical Company Plans Biotech Startup for Clinical Development

Switzerland-based biopharmaceutical Actelion Ltd. recently announced plans to start a biotech separate from the main company. Targeted to "undertake the clinical development of its non-core compounds," the startup will be led by Actelion's former chief medical officer as part of a management restructuring.

According to Actelion, "its first drug Tracleer®, an orally available dual endothelin receptor antagonist," was approved as a therapy for pulmonary arterial hypertension and is marketed in nations throughout the world, including Australia, Canada, European Union member states, Japan, Switzerland, and United States. Founded in 1997, Actelion is devoted to "science related to the endothelium—the single layer of cells separating every blood vessel from the blood stream." *See Actelion Press Release,* June 7, 2011; *InPharm*, June 20, 2011.

Pharmaceutical Companies Announce Licensing Agreement for Hepatitis C Drugs

Massachusetts-based Vertex Pharmaceuticals and San Francisco-based Alios BioPharma have entered a worldwide licensing agreement aimed at developing new combinations of medicines for hepatitis C. According to the companies, Alios will receive a $60-million upfront payment from Vertex for exclusive rights to drug candidates ALS-2200 and ALS-2158.

"In addition, Alios would be eligible to receive research and development milestone payments up to $715 million if both compounds are approved," according to a joint press release. "Vertex expects to pay approximately $35 million in development milestones in 2011. Alios is also eligible to receive up to $750 million in sales milestones on sales of all approved medicines under the collaboration. The agreement also includes tiered royalties on product sales."

Vertex is apparently hoping to create an all-oral, interferon-free, combination therapy that could improve the safety, efficacy and ease of administration for hepatitis C patients, according to Alios founder and CEO Lawrence Blatt. "We look forward to initiating clinical development later this year." *See Vertex Pharmaceuticals* and *Alios BioPharma Press Releases,* June 13, 2011.

INVESTOR NEWS

Life Sciences Company Completes $1.5 Million Initial Funding Round

Using technologies discovered at the University of Maryland, Plasmonix, Inc., a life sciences startup, has reportedly raised $1.5 million of a planned $2 million Series A equity financing. The biotech is apparently working to commercialize testing technology called Metal Enhanced Fluorescence, which can detect heart attacks, sexually transmitted diseases and *Salmonella* in the span of 20 seconds.

"Fluorescence is the most prevalent molecular and cellular detection technology used today in medical research and clinical diagnostics," Plasmonix CEO William Gust was quoted as saying. He predicted that the company's ability to increase fluorescent signals will alter the medical research and clinical diagnostics landscape. *See CityBizList,* June 20, 2011; *The Baltimore Sun*, June 22, 2011.

Cincinnati Investor Closes $4.4 Million Fund to Invest in Startups

Cincinnati-based CincyTech, a venture development company that invests in startup biotech, information technology and advanced manufacturing businesses, has announced the closing of a $4.4 million Fund II targeted for 10 to 12 new startups in southwest Ohio. "The timing of Fund II's closing is crucial because we have such an active pipeline of potential investments," said CincyTech president Bob Coy. CincyTech Fund I, launched in 2007 with $10.4 million, reportedly provided funding to 24 companies that created more than 150 jobs in the region. *See CincyTech Press Release,* June 22, 2011.

BUSINESS CLIMATE

Kansas City-Area Companies Employ 9,000 and Generate $1.33 Billion for Drug Research

According to a new **study**, contract research organizations and contract service providers in a multi-county, bi-state region near Kansas City generate $1.33 billion annually and employ 9,000 to meet the testing and consulting needs of major drug companies and biotech startups. With some 70 companies involved in drug discovery, clinical trials, manufacturing, marketing, and regulatory consulting, the Kansas City region's life sciences activity reportedly surprised the Massachusetts-based company that conducted the study.

David Vranicar, interim CEO of the Kansas Bioscience Authority (KBA), one of the organizations that commissioned the study, said he was also surprised by the results even though he "knew there was a wealth of contract research and service activity in the region." Vranicar noted that equally significant to revenue generation was the region's contracting diversity, "spanning every stage of drug development required to identify and bring new drugs and devices to market." *See Kansas City Business Journal* and *KBA Press Release*, June 21, 2011.

LEGISLATION AND REGULATORY DEVELOPMENTS

Australia and New Zealand to Form Joint Drug, Medical-Device Regulatory Agency

The Australian and New Zealand governments have reportedly developed a five-year plan to create a joint agency that will regulate medicines, medical devices and new medical interventions, such as cellular therapy. In a statement announcing the initiative, New Zealand Prime Minister John Key said, "We want to move into a situation where all medicines and medical devices are specifically approved for New Zealanders before they are used. Currently, medicines are subject to this approval but medical devices are listed on a notification database which should be improved—the establishment of this

new agency provides the opportunity to do so." The agency, to be called the Australia New Zealand Therapeutic Products Agency, could include oversight of natural health products in addition to conventional therapies, although creation of the joint agency does not depend on whether these products are ultimately placed under its umbrella, according to Key. *See PM John Key Press Release*, June 20, 2011; *MassDevice*, June 22, 2011.

G20 Agriculture Ministers Sidestep Biofuels Issues in Paris

While the U.S. Congress is trying to balance the budget with cuts to programs subsidizing bio-based fuels and infrastructure, G20 agricultural ministers meeting in Paris to address a continuing global food supply crisis issued a declaration that failed to reach an accord on whether or how to cut or end biofuel subsidies. The ministers have agreed to "continue to address the challenges and opportunities posed by biofuels." International agencies contend that precipitous rises in the price for basic food commodities over the past four years have been driven by the diversion of food crops to fuel production.

According to a news source, U.S. Agriculture Secretary Tom Vilsack expected to defend the country's biofuel policy in G20 meetings, noting that the United States is moving toward fuels that do not rely on food crops, but are instead made with corn stover and switchgrass. Still, 37 percent of the U.S. corn crop went to ethanol in 2010, and that percentage will not decrease in 2011. Vilsack also apparently believes that the congressional biofuels debate is not over due to the administration's strong financial support for projects developing next-generation fuels. *See Des Moines Register*, June 20, 2011; *Reuters* and *The New York Times*, June 23, 2011.

FDA Proposes Amendments to Sterility Testing for Biological Products

The Food and Drug Administration (FDA) has issued a proposed rule amending the sterility test requirements for biological products, including vaccines and stem-cell treatments.

Aimed at providing manufacturers with "greater flexibility to encourage use of the most appropriate and state-of-the-art test methods," the proposal is part of FDA's efforts to review and update biologics regulations as necessary. FDA requests comments by September 19, 2011.

According to FDA, manufacturers of cell and gene therapy products "may benefit from sterility test methods with rapid and advanced detection capabilities." To ensure that biological products are sterile, the proposed rule addresses testing of novel and currently approved products and urges manufacturers to adopt latest test methods tailored to specific products with appropriate sample sizes. Recognizing that final containers supply the most-appropriate material to test, the proposed rule would eliminate sterility

testing for most bulk material. It also calls for repeat sterility tests to occur only once for each lot.

FDA plans to maintain current exceptions to sterility test requirements for whole blood, Cryoprecipitated AHF, platelets, red blood cells, plasma, source plasma, smallpox vaccine, reagent red blood cells, anti-human globulin, and blood grouping reagent. "However, we request comment on whether any of these current exceptions should be removed," FDA said. "For example, we specifically request comment on whether to remove the exemption for platelets. Bacterial contamination of platelets is a recognized public health risk and the blood collection industry has already called for and implemented methods to detect and limit or inactivate bacteria in platelet components. Requiring testing for platelets would be consistent with these industry practices." *See Federal Register,* June 21, 2011.

SEC Adopts Investing Amendments

The Securities and Exchange Commission (SEC) has adopted implementing rules under the Dodd-Frank Wall Street Reform and Consumer Protection Act including, by a unanimous vote, a new definition for venture capital funds that will exempt advisers who manage qualified funds from the registration and reporting requirements applicable to many hedge funds and private equity firms.

According to SEC, the rules (i) "require advisers to hedge funds and other private funds to register with the SEC," (ii) "establish new exemptions from SEC registration and reporting requirements for certain advisers," and (iii) "real-locate regulatory responsibility for advisers between the SEC and states." SEC also amended rules to expand disclosure by investment advisers, "particularly about the private funds they manage," and revised its "pay-to-play" rule.

SEC now defines "venture capital fund" as a private fund that invests primarily in "qualifying investments"—generally shares in private companies—but may also invest in a "basket" of non-qualifying investments of up to 20 percent of its committed capital and hold certain short-term investments. In addition, a venture capital fund (i) "is not leveraged except for a minimal amount on a short-term basis"; (ii) "does not offer redemption rights to its investors"; and (iii) "represents itself to investors as pursuing a venture capital strategy." A grandfather clause allows funds that started raising money last year to be automatically considered as venture capital funds.

"The rules implement a transitional exemption period so that private advisers, including hedge fund and private equity fund advisers, newly required to register do not have to do so until March 20, 2012," according to SEC. "The rules regarding exemptions for venture capital fund and certain private fund advisers are effective July 21, 2011." *See SEC Press Release* and *The New York Times,* June 22, 2011.

LITIGATION

Patentability of Medical Treatment Claims to Be Heard by U.S. Supreme Court

The U.S. Supreme Court has agreed to review a Federal Circuit Court of Appeals ruling that methods for determining the optimal dosage of thiopurine drugs used to treat gastrointestinal and non-gastrointestinal autoimmune diseases recite patentable subject matter under 35 U.S.C. § 101. *Mayo Collaborative Servs. v. Prometheus Labs. Inc.*, No. 10-1150 (U.S., *cert. granted* June 20, 2011).

The specific question presented is "[W]hether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve 'transformations' of body chemistry." The method at issue involves administering a drug, determining the level of the drug in a patient and deciding whether the amount of the drug should be increased or decreased.

The Federal Circuit decided that the method was patentable after reconsidering the question on remand from the U.S. Supreme Court in light of *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), which rejected "the machine-or-transformation test as the sole, definitive test for determining patent eligibility of a process under § 101." Additional details about the Federal Circuit's ruling appear in Issue 5 of this *Bulletin*. According to the Mayo Clinic, which sought to invalidate Prometheus Laboratories patents, the case involves "whether a patentee can monopolize basic, natural biological relationships."

SCOTUS to Consider What New Evidence May Be Introduced in Section 145 Proceeding

The U.S. Supreme Court has agreed to hear whether an unsuccessful patent applicant may introduce new evidence in a civil action filed under 35 U.S.C. § 145 against the director of the U.S. Patent and Trademark Office (USPTO), where the evidence could have been presented to the agency in her patent application. *Kappos v. Hyatt*, No. 10-1219 (U.S., *cert. granted* June 27, 2011). USPTO Director David Kappos also asks the Court to consider whether, when new evidence is introduced under Section 145, the district court must defer to USPTO's previous decision on the factual issues to which the evidence relates.

According to the Federal Circuit, from which the appeal was taken, section 145 places no constraints on the evidence that may be introduced and is not limited, as USPTO argued, only to evidence "that could not reasonably have been provided to the agency in the first instance." The civil action procedure is one of two methods that dissatisfied patent applicants may employ to obtain court review of a Board of Patent Appeals and Interferences decision.

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The applicant may simply file an appeal to the Federal Circuit, which reviews the board's decision on the basis of the USPTO evidence and record, or the applicant may file a section 145 civil action.

The Federal Circuit noted that the section 145 civil action is a "hybrid." It is not an appeal, according to the court, but it is "also not an entirely de novo proceeding. Issues that were not considered by the Patent Office cannot be raised with the district court in most circumstances, and if no new evidence is introduced, the court reviews the action on the administrative record, subject to the court/agency standard of review." If new evidence is introduced after the close of the administrative proceedings, "the district court reviews that issue de novo." The U.S. Supreme Court will consider the matter during its 2011-2012 term.

NEWS BYTES

The U.S. Patent & Trademark Office (USPTO) announces a pilot Patent Prosecution Highway (PPH) project with the Israeli Patent Office to allow expedited examination proceedings in one country where the other has ruled that at least one claim in an application is patentable.

The USPTO announces an expanded pilot Patent Cooperation Treaty (PCT) PPH project with the Korean Intellectual Property Office. A positive PCT determination on an application may now be used to fast track the patent-approval process in both the United States and Korea.

The USPTO announces a pilot PCT-PPH project with the Nordic Patent Institute. The project will allow the USPTO to benefit from PCT work previously done by the institute, thus reducing the examination workload and improving patent quality.

OFFICE LOCATIONS

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

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