Shook, Hardy & Bacon L.L.P.

ISSUE 29 | FEBRUARY 16, 2012

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

USPTO Proposes New Rules of Trial and Appellate Practice Under AIA

The U.S. Patent and Trademark Office (USPTO) has issued proposed rules of practice to implement sections of the America Invents Act (AIA) that provide for trials before the Patent Trial and Appeal Board and address judicial review of board decisions. Comments are requested by April 9, 2012.

According to USPTO's notice, "the proposed rules would provide a consolidated set of rules relating to Board trial practice for *inter partes* review, post-grant review, derivation proceedings, and the transitional program for covered business method patents by adding a new part 42 including a new subpart A to title 37 of the Code of Federal Regulations. The proposed rules would also provide a consolidated set of rules to implement the provisions of the Leahy-Smith America Invents Act related to seeking judicial review of Board decisions by adding a new part 90 to title 37 of the Code of Federal Regulations." Separate rulemakings address proposed rules specific to *inter partes* review, post-grant review, the transitional program for covered business method patents, and derivation proceedings. Information about those individual proposals appears in the "News Bytes" section of this *Bulletin*.

Recently commenting about how the new patent reforms may affect biopharmaceutical companies, Shook, Hardy & Bacon IP Partner John Garretson pointed to provisions allowing third-party challenges under the new *inter partes* review. He suggested that the rules could generate more challenges to patents by competitors who might find the procedure a less costly alternative to litigation. And with the promise of more expeditious post-grant proceedings, Garretson believes that "courts may be more amenable to granting stays to wait for the administrative proceedings to conclude." *Genetic Engineering & Biotechnology News*, February 13, 2012.

USPTO has also requested comments on its practice guide for proposed trial rules. The document is intended "to advise the public on the general framework of the proposed regulations, including the structure and times for taking action in each of the new proceedings" discussed above. Comments on the practice guide are also requested by April 9. *See Federal Register*, February 9, 2012.

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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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If you have questions about this issue of the Report, or would like to receive supporting documentation, please

INVESTOR NEWS

Massachusetts Biotech Adds $6.3 Million Targeted to Stem Cell Reagents

Cambridge-based Stemgent Inc. has reportedly gained just under $600,000 in its last funding round, raising its total thus far to $6.3 million targeted toward expanding its licensed intellectual property around stem cell reagents. In all, the company plans to reach an $8.8 million goal for the round. A Securities and Exchange Commission filing apparently shows that eight unnamed backers participated; listed as related persons are board members Harold Werner and Augustine Lawlor of HealthCare Ventures LLC, and Ralph Christoffersen of Morganthaler Partners of Ohio.

Stemgent CEO Ian Ratcliffe told a news source that the funds would move forward "our existing operations" to allow for continued expansion of products. The company evidently has licenses related to stem cell reagents from institutions such as the Massachusetts Institute of Technology, Harvard University and Scripps Research Institute in La Jolla, California. *See Mass High Tech,* February 1, 2012.

Biopharmaceutical Secures $2.2 Million to Develop Pancreatic Cancer Vaccine

Norwegian biopharmaceutical Targovax AS has reportedly secured $2.2 million (13 MNOK) in private capital to develop a pancreatic cancer vaccine called TG01. The funding comes from a consortium that includes the Radium Hospital Research Foundation, Birk Venture, RO Invest, and existing owners.

According to Targovax, the company was created in October 2010 to develop TGO1, which is based on research conducted during the 1990s "when the vaccine was tested in patients with good results." Targovax CEO Hanne Mette Kristensen said that the private and public funding "gives a good signal regarding the project's quality. This financing will enable us to submit an application for clinical studies, and to produce the TG according to pharmaceutical standards. We will be ready to include the first patients in the last quarter of 2012." *See Targovax Press Release*, January 25, 2012.

BUSINESS CLIMATE

Life Sciences Startups Generate More Capital in 2011, Biotech Job Ads Down Slightly in Q4

According to data analyzed by PricewaterhouseCoopers (PwC) in a new report titled "Zigzagging Upward," venture capital funding increased 21 percent during 2011 for the life sciences sector, including biotechnology and medical device companies. More than $7.5 billion was invested in 785 life sciences deals overall, but funding and deal volume decreased in the third

quarter. During the fourth quarter (Q4), life sciences investments increased by 34 percent compared with Q4 2010, and investments in biotechnology accounted for 72 percent of the funding, with medical devices representing just 28 percent. Noting that a few venture-backed IPOs involved life sciences companies, a PwC spokesperson said, "We did see the IPO window crack slightly during the fourth quarter of 2011 . . . However, at this point in time, M&A deals continue to offer more exit opportunities for Life Sciences companies than IPOs." *See PwC News Release*, February 2, 2012.

In a related development, the February 2012 issue of *Nature Biotechnology* includes data indicating that while the number of biotech sector jobs advertised in Q4 2011 decreased slightly from the third quarter, pharmaceutical sector hiring needs were about the same. Areas seeing new investments and job growth include China and the U.S. Northeast. The New York Genome Center, scheduled to open in the spring, involves 11 New-York based medical centers that will create a research facility in Manhattan and share clinical and genomic data and resources. A Maine-based laboratory is apparently planning to create a center for personalized medicine and genomics in Connecticut with a budget of about $1.1 billion.

Companion Diagnostics in Personalized Medicine Facing Explosive Growth

Biotech and life sciences market researcher TriMarkPublications.com has reportedly predicted in a newly published report that the market for companion diagnostics "will explode as the personalized medicine market catapults to $42 billion by 2015." Companion diagnostics are assays that use genetic variation, including gene expression variability and other molecular signatures, to distinguish patient responses to particular drugs or biologic agents and thus can provide a basis for optimizing therapy options. They will also apparently "play an increasingly important role in cancer treatments." *See Marketwire*, February 2, 2012.

Indian Official Calls for Passage of Biotech Regulatory Legislation and Increased VC Funding

A biotechnology industry spokesperson has reportedly pointed to the lack of a proper regulatory framework in India as one of several hurdles the industry will have to surmount to grow. Kiran Mazumdar, profiled in Issue 27 of this *Bulletin,* reportedly said, "Only a proper regulatory framework would help realize these expectations. The regulatory system was necessary to provide support for innovation." During remarks at the Bangalore India-Bio 2012 conference, she also apparently indicated that enormous opportunities for growth in the biotechnology energy sector could reduce the nation's dependence on fossil fuels.

The secretary for India's Department of ITT and Science and Technology reportedly echoed Mazumdar, observing that, "[t]he regulations for the [biotechnology] sector should have been in place. I hope the long-pending National Biotechnology Regulatory Authority of India Bill, before the Parliament, would go through soon." He claimed that the government will issue "strategy papers to address the issue of bio-manufacturing by May 30 or latest by June 15." Secretary M.K. Bahn also indicated that the country needs inexpensive cancer treatments which the government cannot afford, thus making private sector participation inevitable. *See Business Standard*, February 7, 2012.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FDA Issues Draft Biosimilars Guidance, Gaps Leave Practitioners Wondering

The Food and Drug Administration (FDA) has issued three draft guidance documents to implement health-care reform law provisions requiring the creation of an abbreviated approval pathway for biological products that are similar to an FDA-licensed biological product. Comments are requested by April 16, 2012.

The documents relate to (i) how FDA will approach a biosimilarity determination (scientific considerations) (ii) the agency's "current thinking on factors to consider when demonstrating that a proposed protein product is highly similar to a reference product licensed under section 351(a) of the Public Health Service Act (PHS Act) for purposes of submitting a marketing application under section 351(k) of the PHS Act," (quality considerations) and (iii) questions and answers relating to FDA's interpretation of the Biologics Price Competition and Innovation Act of 2009 [BPCIA]," which established the requirements for an application for proposed biosimilar products and an application or a supplement for a proposed interchangeable product. The BPCIA contains the 12-year exclusivity period for biologic products that President Barack Obama (D) has proposed reducing in his 2013 budget proposal.

Legal commentators have observed that the guidance documents lack certain details that will ultimately determine the cost of biosimilar development. Among other matters, FDA failed to address in any detail the issues of clinical trials and interchangeability. While the agency did stress that it will take a "totality of the evidence" approach, that is, it will review all available data, even if relatively small, and that sponsors may be able to use data from license applications filed in Europe, it did not clarify what animal or human trials would be required. Regarding interchangeability, Congress set the evidentiary bar higher, requiring that sponsors show a patient can switch from the reference products to the biosimilar and back again with no adverse effects. FDA's failure to address this aspect of biosimilarity left a "gaping hole," according to Shook, Hardy & Bacon IP Partner John Garretson. He suggests that further agency guidance on this issue is "the other shoe that's going to drop."

Garretson also noted that while the draft guidance is "an important step, I don't know that people are going to immediately jump in the pool. It's not detailed or specific enough for people to say, 'We have the critical information we didn't have before,'" and now we can submit an application. FDA has yet to receive an application to approve a biosimilar drug, although nine applications have been filed for clinical trials. The long-awaited guidance is considered, nevertheless, an important step in the development of an industry that is expected to generate $3.7 billion in sales by 2015. *See FDA News Release* and *Reuters*, February 9, 2012; *Law360*, February 10, 2012.

Meanwhile, the Congressional Research Service has issued a report for Congress titled "**Follow-On Biologics: The Law and Intellectual Property Issues**." It "reviews the BPCIA within the context of intellectual property and innovation issues" by providing a introduction to the biologics industry, the law's regulatory and intellectual property provisions, the potential market for biosimilars, and possible industry responses to the legislation. The authors conclude that the BPCIA "is a complex and novel statute. Resolution of the scientific and legal issues that this legislation raises will likely engage the courts and the FDA for many years to come. . . . As a result, marketplace availability of significant numbers of follow-on biologics may well be a long-term proposition."

Pay-for-Delay Deals and Biologics' Exclusivity Period Part of President's Proposed 2013 Budget

According to a news source, President Barack Obama's (D) proposed 2013 budget includes provisions that would set new policies pertaining to generic medications and biologics. The president seeks to authorize the Federal Trade Commission to stop companies from settling patent infringement lawsuits with pay-for-delay deals under which generic manufacturers agree to postpone selling their products in exchange for payments by brand-name manufacturers. The proposal reportedly claims that prohibiting these deals would save federal health care programs $11 billion over the next 10 years by making generic drugs more readily available.

The budget proposal also apparently calls for reducing the 12-year exclusivity period for biologics to seven years, claiming that this would realize $4 billion in savings over 10 years. And the president is calling for a ban on other periods of exclusivity for brand biologics effected through minor changes to product formulations, a practice referred to as "evergreening." The president of a pharmaceutical industry trade organization reportedly criticized the proposals, claiming they would negatively affect innovation and job creation. As to the pay-for-delay provisions, he said, "Patent settlements are a vital aspect of a patent owner's ability to protect intellectual property. Without settlements, costly litigation could keep these generics from being available to patients for years." He also opposed reducing the exclusivity period for

biologics, saying they are critical to the development of cutting-edge treatments and deserve protection. *See Law360*, February 13, 2012.

Proposed Legislation Would Streamline Compliance Regulations for Medical Devices

U.S. Senators Bob Casey (D-Pa.) and John McCain (R-Ariz.) have introduced a bill (S. 2067) that would "remove burdensome regulations that hurt medical device manufacturers."

Current regulations call for medical device manufacturers to put new products through a Food and Drug Administration (FDA) review process that could take years because the agency must determine that no similar devices are already on the market, "even if it is already known that a similar device does not exist," the senators said in a joint press release.

Titled the Safe, Efficient and Transparent Medical Device Approval Act, or SET Device Act, the bill would (i) "streamline the FDA review process by allowing medical device manufactures to submit new products for direct approval without the burdensome review to determine if there are similar products already on the market" and (ii) "address safety issues by ensuring that medical devices on the market before current safety classification systems existed are properly classified in a timely manner."

"The FDA's current approval process for medical devices can be cumbersome, inconsistent and far too lengthy for patients who need innovative technologies and for the companies that develop them," McCain said. "With the U.S. medical device industry struggling to maintain international leadership, this legislation streamlines the outdated regulatory approval process to improve patients' access to safe and effective medical devices." *See Press Releases of Senators McCain and Casey*, February 2, 2012.

Meanwhile, U.S. Senators Herb Kohl (D-Wis.), Chuck Grassley, (R-Iowa) and Richard Blumenthal (D-Conn.) have written a letter to the Office of Management and Budget (OMB) urging the release of "a key new rule on post-market surveillance of medical devices."

In July 2011, FDA sent OMB proposed regulations that would require a Unique Device Identifier (UDI) on all medical device labels designed to track the devices through distribution and implantation in patients. OMB usually has 90 days to review and release rules, but has yet to do so, according to the lawmakers.

"Unique Device Identifiers proved an important post-market safety tool that will reduce the time it takes to track and locate problematic devices," Kohl said. "The longer we wait for a system to be in place, the greater the number of patients placed at risk." *See Press Release of Senator Herb Kohl,* February 2, 2012.

In a related development, FDA and medical device industry representatives have reportedly reached a tentative agreement authorizing FDA to collect $595 million in user fees over five years, plus adjustments for inflation. The agency states that under a user fee program, "industry agrees to pay fees to help fund a portion of FDA's device review activities while FDA agrees to overall performance goals such as reviewing a certain percentage of applications within a particular time frame."

After nearly a year of negotiations between FDA and industry, the agreement "strikes a careful balance between what industry agreed to pay and what the FDA can accomplish with the amount of funding proposed," FDA said. The agency plans to develop a package detailing the proposed recommendations and give the public an opportunity to comment before submitting the plan to Congress. *See FDA Press Release,* February 1, 2012.

LITIGATION

Federal Circuit Confirms That Generic ANDA Applications Did Not Infringe Drug Patents

The Federal Circuit Court of Appeals has determined that when generic drug makers seek Abbreviated New Drug Applications (ANDAs) from the Food and Drug Administration (FDA) for uses of patented drugs not covered by the patents, the generics do not infringe the patents. ***AstraZeneca Pharms. LP v. Apotex Corp.*, Nos. 2011-1182, -1183, -1184, -1185, -1186, -1187, -1188, -1189, -1190 (Fed. Cir., decided February 9, 2012)**. So ruling, the court dismissed the patent holder's infringement actions finding it had failed to state a claim under 35 U.S.C. § 271(e)(2) as to the existing ANDA filings and further that its "claims premised on presumed future labeling amendments were not ripe for adjudication."

As to the court's statutory determination, the decision was in accordance with *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), with the court noting that "infringement of method claims under § 271(e)(2) requires filing an ANDA where at least one 'use' listed in the ANDA is claimed in a patent." Here, the drug involved was a statin. The patents mentioned certain diseases for which the drug would be used. FDA approved those uses under the patent holder's new drug application and also determined that the drug could be used for additional conditions. The generic drug makers' ANDAs sought approval for those additional FDA-approved conditions and specifically excluded the patented uses.

Regarding the patent holder's assertion that pharmacists and doctors would eventually prescribe the generic for the patented uses, the court called its argument "unpersuasive. . . . [I]f accepted, these speculative arguments would allow a pioneer drug manufacturer to maintain de facto indefinite exclusivity

over a pharmaceutical compound by obtaining serial patents for approved methods of using the compound and then wielding § 271(e)(2) 'as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent. Generic manufacturers would effectively be barred altogether from entering the market.'"

The court also rejected the patent holder's claim that FDA would eventually require the generic drug makers to include all uses, including those covered by the patents, on their product labels. According to the court, "claims based on presumed future labeling requirements are unripe. . . . [N]othing in the record indicates that the FDA has required [the generic drug makers] to add further indications, and we see no reason to presume that the FDA will do so in the future."

Certiorari Decision on Patent Eligibility for Isolated DNA Could Be Reached February 20

Briefing in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, No. 11-725 (U.S., petition for certiorari filed December 7, 2011), is now complete, and the U.S. Supreme Court is scheduled to consider the matter during its February 17, 2012, conference. The Court could issue a ruling as early as February 20 on whether it will grant review. Additional details about the case, which involves whether human genes are patentable, appear in Issues 18 and 23 of this *Bulletin*. Nine *amicus* briefs have been filed, and the petitioners' final reply brief, filed January 20 by the American Civil Liberties Union and the Public Patent Foundation, urges the Court to simplify the issues and expand the parties with standing to challenge the patent.

NEWS BYTES

The U.S. Patent and Trademark Office issues a proposed rulemaking to implement provisions of the America Invents Act "that create a new derivation proceeding to be conducted before the Patent Trial and Appeal Board." These provisions take effect March 16, 2013, "and apply to applications for patent, and any patent issuing thereon, that are subject to first-inventor-to-file of the Leahy-Smith America Invents Act." Comments are requested by April 10, 2012.

The U.S. Patent and Trademark Office issues a proposed rulemaking to implement provisions of the America Invents Act "that create a new *inter partes* review proceeding to be conducted before the Patent Trial and Appeal Board." These provisions take effect September 16, 2012, and "apply to any patent issue before, on, or after the effective date." Comments are requested by April 10, 2012.

The U.S. Patent and Trademark office issues a proposed rulemaking to implement provisions of the America Invents Act "that create a new post-grant

review proceeding to be conducted before the Patent Trial and Appeal Board." These provisions take effect September 16, 2012, and "generally apply to patents issuing from applications subject to first-inventor-to-file provisions of the Leahy-Smith America Invents Act." Comments are requested by April 10, 2012.

The U.S. Patent and Trademark Office issues a **proposed rulemaking** to implement provisions of the America Invents Act "that create a new transitional post-grant review proceeding for covered business method patents to be conducted before the Patent Trial and Appeal Board." These provisions take effect September 16, 2012; the provisions and regulations issued under them "will be repealed on September 16, 2020, with respect to any new petitions under the transitional program." Comments are requested by April 10, 2012.

The U.S. Patent and Trademark Office issues a **proposed rulemaking** to implement a provision of the America Invents Act "that requires the Office to issue regulations for determining whether a patent is for a technological invention in a transitional post-grant review proceeding for covered business method patents." A covered business method patent "is a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions. This rulemaking provides regulations for determining whether a patent is for a technological invention." The provision takes effect September 16, 2012; the provision and any regulations issued under it "will be repealed on September 16, 2020, with respect to any new petitions under the transitional program." Comments are requested by April 10, 2012.

The Food and Drug Administration **announces** a March 28-29, 2012, meeting of the Endrocrinologic and Metabolic Drugs Advisory Committee in Silver Springs, Maryland. The committee is slated to discuss "the role of cardiovascular assessment in the preapproval and postapproval settings for drugs and biologics development for the treatment of obesity."

The U.S. Patent and Trademark Office **launches** a 12-month pilot program designed as an awards competition targeted to patented technologies that address humanitarian needs. Applications will be accepted from March 1 through August 21, 2012.

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UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Practice Partners Scott Sayler and David Brooks will participate in DRI's Drug and Medical Device Seminar slated for May 10-11, 2012, in New Orleans, Louisiana. Co-sponsored by SHB, the event will feature "trial skills demonstrations, panel discussions of judges overseeing coordinated pharmaceutical proceedings, and litigation insights from leading defenders of drug and device cases." Brooks will present a session titled "When a Good Medical Device Fails: Successfully Defending Medical Device Suits When Causation Is Not in Doubt," which will address the substantive and strategic consideration of defending these cases. Sayler will also deliver remarks as chair of DRI's Drug and Medical Device Committee.

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