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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

FIRM NEWS

Kaplan & Montgomery Publish U.S. Overviews on Pharma Regulation and IP Law

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Harvey Kaplan** and Associate **Evan Montgomery** have published two articles in the Thomson Reuters Life Sciences Multi-Jurisdictional Guide 2014/15. One article, titled "**Medicinal product regulation and product liability in the United States: overview**," addresses an array of regulatory issues, including manufacturing, pricing, clinical trials, marketing, data protection, and product liability. The second, titled "**Pharmaceutical IP and competition law in the United States: overview**," discusses patent, trademark and competition law matters.

IP NEWS

USPTO Proposes Changes to Patent Term Adjustment

In response to the Federal Circuit Court of Appeals ruling in *Novartis AG v. Lee*, summarized in Issue **71** of this *Bulletin*, the U.S. Patent and Trademark Office (USPTO) has **issued** a notice of proposed rulemaking to change its rules of practice. USPTO would revise those rules pertaining to patent term adjustments "to provide that the time consumed by continued examination does not include the time after a notice of allowance, unless the Office actually resumes examination of the application after allowance." USPTO has also proposed changes that would "provide that the submission of a request for continued examination after a notice of allowance has been mailed will constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application and thus result in a reduction of any period of patent term adjustment." Comments are requested by August 18, 2014. *See Federal Register*, June 18, 2014.

Shook, Hardy & Bacon L.L.P.

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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 contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

INVESTOR NEWS

Biotech Raises $60 Million in IPO for Kidney & GI Disease Treatments

Bay Area biotech Ardelyx, Inc. has reportedly raised $60 million in an initial public offering (IPO), selling 4.3 million shares at $14. The company has also granted the underwriters a 30-day option to purchase up to an additional 642,900 shares of common stock at the IPO price. A clinical-stage biopharmaceutical company, Ardelyx focuses on the development and commercialization of small molecule therapeutics to treat kidney and gastrointestinal (GI) disease. Citigroup and Leerink Partners acted as joint book-running managers for the offering, JMP Securitites acted as lead manager and Wedbush PacGrow Life Sciences acted as co-manager. According to a news source, Ardelyx was the only Bay Area company that went public during the third week of June as IPOs in the region have slowed since the beginning of the year. *See Bizjournals.com* and *Biospace.com*, June 19, 2014.

Definiens Secures $20.5 Million from Private Investors to Advance Oncology Diagnostics

Headquartered in both Munich, Germany, and Carlsbad, California, Definiens AG has reportedly raised €15 million (US$20.4 million) in a private financing round led by Wellington Partners, a pan-European venture capital firm whose general partner and managing director will join Definiens' board of directors. With a focus on contributing to the development of personalized medicine, Definiens will use the new funds to advance its tissue phenomics strategy, which involves a "big data approach to develop new tissue-based diagnostic tests for oncology and immunotherapy." The company assists pharmaceutical and biotechnology companies, as well as research institutions, clinical service organizations and pathologists in generating new knowledge and supporting better research decisions. Definiens Chair Gerald Möller said, "The use of state-of-the-art information technology in medicine will dramatically improve the way patients will be diagnosed and treated and the way new drugs and diagnostic tests will be developed." *See Definiens AG News Release*, June 23, 2014.

BUSINESS CLIMATE

Biotech Employment Gains Make Up for Pharma Losses

According to new EP Vantage research, while employment in those companies characterized as "Big Pharma" decreased slightly in the period 2003-2013, biotechnology companies not traditionally considered part of

that group compensated for the losses by more than doubling employment during the decade. The report shows how Big Pharma has changed through industry consolidation and dramatic restructuring, resulting in staff alterations that some had feared would show significant reductions. The mere 3-percent drop represented nearly 31,500 employees; with big biotech and specialty drug makers hiring 130,000, the losses were more than offset. EP Vantage Editor Lisa Urquhart said, "With the focus still on cost cutting in big pharma, if you want a long-term career in the industry, you might be better off with a smaller player." *See EPVantage News Release* and *PharmExec.com*, June 18, 2014.

MoneyTree™ Report Shows Venture Funding Pipeline Open to Biotechs

A Pricewaterhouse Coopers LLP and National Venture Capital Association MoneyTree™ report, based on Thomson Reuters data, shows that biotechnology was the second largest investment arena for venture capitalists during the past two years. More than $4 billion supported 470 deals for an 8-percent increase. The first quarter of 2014 is also on pace with more than 112 such deals completed. The leading areas of interest for corporate and venture funds were, in order, oncology, central nervous system diseases, anti-infectives, metabolic diseases, dermatology, and cardiovascular diseases. According to the report, the venture capitalist is sometimes a pharmaceutical company; some of the largest have separate funding arms that extend their reach into the global scientific community and create the relationships that can complement and expand internal research and development efforts. *See Genetic Engineering & Biotechnology News*, June 20, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Democratic Lawmakers Ask NIH to Disclose Demographic Data for Clinical Trials

Led by Reps. Louise Slaughter (D-N.Y.), Rosa DeLauro (D-Conn.) and Lois Capps (D-Calif.), 22 U.S. House Democrats have **written** to National Institutes of Health (NIH) Director Francis Collins to complain that while ClinicalTrials.gov, "the nation's primary resource for information on publicly and privately supported clinical trials," provides demographic data for select completed trials, it "does not allow for all studies to be analyzed by sex or other demographic data." They note that Congress has required that women and minorities be included in NIH-funded clinical trials "in a manner sufficient to elicit information about individuals of both sexes/genders and diverse racial and ethnic groups and, particularly in NIH-defined Phase III clinical trials, to examine differential effects on such groups." *See Rep. Louise Slaughter News Release*, June 18, 2014.

Considering End-User Interests in Patent-Law Reforms

Seton Hall University School of Law Professor Gaia Bernstein analyzes the rising role of end users in the patent-litigation landscape and argues that they need to be equipped with tools to defend their interests. "**The Rise of the End User in Patent Litigation," *Boston College Law Review* (2014 forthcoming)**. Bernstein is particularly concerned that current congressional proposals to shift fees in patent lawsuits do not adequately consider "the special status of end users."

The characteristics that make end users—e.g., those customers that use patented technologies in their everyday business and are sued by patent assertion entities, or patients and physicians suing to invalidate breast cancer gene patents—vulnerable include a lack of technological sophistication and financial resources. They also "tend to become involved in the patent conflict relatively late in the life of the patent and they are typically one-time players." The author contends that the America Invents Act failed to predict this phenomenon and does not address "the growing role of end users" because most of the new procedures are no longer available when end users become involved in patent conflicts. The article recommends that end-user status be considered as a special factor "that would weigh toward granting fee shifting where the end user is a prevailing party."

FDA Accepts 23andMe 510(k) Application for Single-Condition Health Report

The U.S. Food and Drug Administration (FDA) has reportedly accepted for review 23andMe's submission for the premarket approval of a new medical device (510(k) application)—here, a health report from its DNA collection kits assessing customer risk for Bloom syndrome, an inherited disorder apparently associated with short stature and various cancers that often result in death by the mid-20s. Details about FDA's order that the company cease marketing its home saliva test kits as unapproved medical devices because they were "intended for use in the diagnosis of disease or other conditions" appear in Issue **69** of this *Bulletin*. According to 23andMe Chief Legal and Regulatory Officer Kathy Hibbs, this marks "an important step in our work with the FDA in the coming months. Once cleared, it will help 23andMe, and the FDA, establish the parameters for future submissions. More importantly, for our customers, it marks a baseline on the accuracy and validity of the information we report back to them." *See 23andMe Blog* and *Forbes*, June 20, 2014.

FDA Inspection Finds CGMP Violations at Bangalore Facility

The U.S. Food and Drug Administration (FDA) has **issued** a warning letter to the president and CEO of Apotex, Inc., claiming that the agency's inspection of the company's Bangalore, India-based pharmaceutical manufacturing facility revealed deviations from current good manufacturing practice (CGMP) for the manufacture of active pharmaceutical ingredients (APIs). The letter specifically cites the company's failure to (i) "maintain complete data derived from all laboratory tests conducted to ensure compliance with established specifications and standards," (ii) "investigate and document out-of-specification results," (iii) "include adequate documentation during complaint investigation," and (iv) "record activities at the time they are performed."

Noting that the company has committed to hiring a third-party auditor to address these issues, the letter also includes actions this consultant should take. And FDA requests that the company provide a list of all the batches of APIs in distribution and those intended to be shipped to the United States market relying on "missing, inaccurate, or unreliable test data," as well as take steps to notify the Center for Drug Evaluation and Research Drug Shortages Program to allow FDA "to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products." In addition to barring products from the facility from entry into the United States, FDA indicates that it "may withhold approval of any new applications or supplements listing your firm as an API manufacturer."

FDA Draft Guidance Addresses Drug and Device Online Communications

The U.S Food and Drug Administration (FDA) has **issued** draft guidance titled "Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices." The document addresses the agency's "current thinking on how manufacturers, packers, and distributors (firms) of prescription human and animal drugs (drugs) and medical devices for human use (devices), including biological products, that choose to present benefit information should present both benefit and risk information within advertising and promotional labeling of their FDA-regulated medical products on electronic/digital platforms that are associated with character space limitations, specifically on the Internet and through social media or other technological venues." Comments are requested by September 16, 2014.

FDA has also **issued** for public comment draft guidance titled "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices." This guidance discusses how these stakeholders "should respond, if they choose to

respond, to misinformation related to a firm's own FDA-approved or cleared products when that information is created or disseminated by independent third parties, particularly on the Internet or through social media platforms. Comments on this draft guidance are requested by August 18, 2014. *See Federal Register*, June 18, 2014.

LITIGATION

Supplier Sentenced for Illegal Sales of Non-Approved Drugs

According to the U.S. Department of Justice, a federal court in Virginia has sentenced a U.S. citizen, who owned and operated several companies in Canada, the United Arab Emirates and Afghanistan, following his guilty plea to charges of introducing misbranded drugs into the United States. Mirwaiss Aminzada will serve a 15-month term of imprisonment, undergo supervised release for one year and pay restitution of more than $580,000. He allegedly used his companies to obtain chemotherapy and cosmetic drugs intended for Middle Eastern markets and sold them to Gallant Pharma, an unlicensed drug wholesaler, for resale in the United States. A Pakistani employee purportedly altered the drugs' packaging to conceal evidence of their foreign source. He also allegedly said in an email to Aminzada that he was unable to keep chemotherapy drugs requiring refrigeration cold because electrical service in Peshawar, Pakistan, was intermittent.

Court records also reportedly showed that Aminzada "was the source of vials of tampered Botox that were missing safety caps, contained an unusual jelly-like substance and bore mismatched lot numbers and expiration dates." This product also entered the U.S. supply chain through Gallant and was administered to some patients in New England. Twelve defendants associated with Gallant Pharma have been convicted, and two additional defendants named in the related indictment are apparently at large and believed to be in Canada. *See U.S. Department of Justice Press Release*, June 6, 2014.

New Infringement Lawsuit Filed to Protect BRCA1 and BRCA2 Patents

Myriad Genetics has brought a new infringement lawsuit against a company offering a next-generation sequencing test that analyzes the BRCA1 and BRCA2 genes associated with various cancers, including breast and ovarian. *Univ. of Utah Research Found. v. Pathway Genomics*, No. 14-0442 (U.S. Dist. Ct., D. Utah, Cent. Div., filed June 13, 2014). Claiming willful infringement, Myriad seeks injunctive relief, damages and a finding that the case is "exceptional" to support enhanced damages and attorney's fee awards. According to a news source, Pathway is one of a number of

laboratories Myriad has sued since the U.S. Supreme Court found that certain of its claims were patent eligible. Among the others are Ambry Genetics, Laboratory Corp. of America, Quest Diagnostics, Gene by Gene, and GeneDX. In a statement, Pathway reportedly indicated that it would "vigorously defend" Myriad's claims. *See genomeweb.com*, June 16, 2014.

NEWS BYTES

The U.S. Patent and Trademark Office (USPTO) **requests** nominations for open three-year positions on the Patent Public Advisory Committee and Trademark Public Advisory Committee. These committees review USPTO's policies, goals, performance, budget, and user fees; members must represent small and large entity applicants in the United States. Nominations are requested by July 25, 2014.

The U.S. Food and Drug Administration **issues** a draft document titled "Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products." Intended for investigational new drug application sponsors and applicants for a biologics license application or its supplementation, the document sets forth "recommendations on considerations when assessing whether to submit an Environmental Assessment (EA) for gene therapies, vectored vaccines, and related recombinant viral or microbial products." It also indicates what information should be included in an EA and what to expect once an EA is filed. Comments are requested by September 18, 2014.

The National Institutes of Health **seeks** "available data and information on devices and/or technologies currently used for identifying potential inhalation hazards. Submitted information will be used to assess the state of the science and determine the technical needs for a dynamic nonanimal system to assess the potential toxicity of inhaled chemicals and nanomaterials." The deadline for submissions is July 18, 2014.

The U.S. Food and Drug Administration **issues** the first part of its finalized industry guidance on the global unique device identification database, a critical component of the unique device identification system mandated under the Food and Drug Administration Safety and Innovation Act of 2012. The remaining sections of the draft guidance, issued in September 2013 for public comment, will be finalized in one or more additional parts and published at a later date. The first part includes those sections that generated the most comments or questions. Labelers are responsible for submitting information to the database, and the guidance provides them with general information on obtaining a database account and beginning their initial submissions.

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The U.S. Food and Drug Administration (FDA) **seeks** comments on draft guidance titled "Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices." It "describes FDA's current thinking on recommended practices for drug manufacturers and their representatives to follow when distributing to health care professionals or health care entities scientific or medical journal articles that discuss new risk information for approved prescription drugs for human use, including drugs licensed as biological products, and approved animal drugs." Comments are requested by August 11, 2014.

The U.S. Food and Drug Administration **requests** comments on draft industry guidance titled "Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification." The guidance is intended to assist "certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers)," in identifying a product that is illegitimate or at high risk of illegitimacy and notifying the agency and all immediate trading partners within 24 hours of making this determination. Comments on the draft guidance should be submitted by August 11, 2014, to be considered in its finalization.

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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.

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