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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Federal Circuit Rules on Patent-Term Extensions

The Federal Circuit Court of Appeals has issued a ruling that interprets and applies patent-law provisions that extend "patent terms to compensate for certain application-processing delays caused by the PTO [U.S. Patent and Trademark Office]." ***Novartis AG v. Lee*, Nos. 2013-1160, -1179 (Fed. Cir., decided January 15, 2014)**. Its decision distinguishes between delays attributable to the applicant and those attributable to PTO.

The law allows PTO three years to process a patent application and extends the patent term one day for each day that PTO fails to issue the patent after the end of the three-year period, subject to certain exclusions, including requests for continued examination (RCE). 35 U.S.C. § 154(b). It also provides applicants with a 180-day window to seek judicial review of the PTO director's patent-term adjustment determination. Here, Novartis filed four lawsuits claiming that, for 23 of its patents, the PTO director improperly determined the amount of the patent-term adjustment. Novartis argued that the determinations were based on flawed statutory interpretations as they applied to an applicant's RCE.

The Federal Circuit initially disagreed with Novartis that filing an RCE should render the 180-day limitation inapplicable, finding the company's interpretation too narrow and based on an unreasonable inference. The court also disagreed that "once three calendar years from the application-filing date have come and gone, time spent in the PTO after that date must be added to the patent term even if it is time spent on a continued examination requested after that date." To the contrary, the court determined that the patent-term adjustment "should be calculated by determining the length of time between application and patent issuance, then subtracting any continued examination time [and other exclusions] and determining the extent to which the result exceeds three years."

The court disagreed with PTO that "any time up until the patent issues, even after allowance, should be excluded from the adjustment awarded to the patentee," stating, "The common-sense understanding of 'time

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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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consumed by continued examination,' 35 U.S.C. § 154(b)(1)(B)(i), is time up to allowance, but not later, unless examination on the merits resumes." Accordingly, the court affirmed the district court's rulings as to the untimeliness of the reviews Novartis filed for 15 patents and remanded the patent-term adjustments for three patents to the district court for a redetermination.

INVESTOR NEWS

Acceleron Raises $120 Million to Develop Cancer and Rare Disease Therapeutics

Acceleron Pharma Inc., a clinical-stage biopharmaceutical company that develops investigational drugs for cancer and rare diseases, has reportedly raised $120 million in a stock offering, doubling the Cambridge, Massachusetts-based company's cash on hand of $116 million as of September 30, 2013. Acceleron has also granted underwriters Citigroup and Leerink Partners a 30-day option to purchase up to an additional 360,000 shares of common stock at the public offering price of $50 per share.

Company partner Celgene reportedly began a seventh mid-stage trial of Acceleron's lead drug, Sotatercept, in December. While the trial focuses on hemodialysis patients with end-stage kidney failure, Sotatercept is also apparently undergoing testing as a treatment for anemia in rare blood diseases, including beta-Thalassemias, myelodysplastic syndromes and Diamond Blackfan, in addition to chronic kidney disease and multiple myeloma. *See Acceleron Pharma Inc. Press Release,* January 22, 2014; and *Boston Business Journal*, January 23, 2014.

Atossa Genetics Inc. Prices Public Offering

Atossa Genetics Inc., a Seattle, Washington-based developer of products and services related to breast health, has announced a public offering of approximately 5.8 million units at $2.40 per unit. The company expects to raise $14 million in gross proceeds, which will be used for general corporate purposes, including a re-launch of its ForeCYTE Breast Aspirator and development of other products such as the FullCYTE Breast Health Test, NextCYTE Breast Cancer Test, ArgusCYTE Breast Health Test, and the company's intra-ductal treatment program. Atossa reportedly recalled its ForeCYTE Breast Health Test and Mammary Aspiration Specimen Cytology Test device in 2013 after the U.S. Food and Drug Administration expressed concerns about its use and the way the company was marketing it. Dawson James Securities, Inc. is the sole book-running manager for the offering. *See Atossa Genetics Inc. News Release* and *GenomeWeb.com*, January 24, 2014.

Biotech Raises $57.4 Million in IPO

GlycoMimetics, Inc., a biotechology company focusing on the development of treatments for blood cancers and inflammatory diseases, has closed its initial public offering (IPO) of more than 8 million shares of common stock, raising $57.4 million at an IPO price of $8 per share. Underwriters Jefferies LLC and Barclays Capital Inc. exercised their option to purchase up to 1-million additional shares of common stock. Stifel acted as co-lead manager, and Canaccord Genuity Inc. acted as co-manager. The company reportedly plans to use the proceeds to fund clinical research of its lead candidate, GMI-1271, to treat acute myeloid leukemia. *See SmartBrief.com,* January 13, 2014; and *GlycoMimetics, Inc. News Release*, January 15, 2014.

NanoString Seeks $55 Million to Advance Breast Cancer Test

NanoString Technologies, Inc., which develops life-science research tools, including analytical systems used by cancer researchers to study the activity of genes in small tissue samples, has announced the pricing of its follow-on public offering of $55 million of common stock at $18.50 a share. It has also granted underwriters the option to purchase up to $8.25 million more of its common stock. The Seattle, Washington-based company plans to use the proceeds to further commercialize its Prosigna™ Breast Cancer Prognostic Gene Signature Assay by establishing a dedicated oncology sales force and expanding the test's clinical utility. Details about the company's previous funding initiatives appear in Issue **25** of this *Bulletin. See NanoString News Release*, January 23, 2014.

Biopharmaceutical Seeks $75 Million in IPO

According to a news source, Lexington, Massachusetts-based Concert Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company that develops drugs to treat a range of diseases, including multiple sclerosis, diabetic kidney disease, inflammatory diseases, neurologic and psychiatric diseases, and narcolepsy, seeks to raise $75 million in an initial public offering (IPO). UBS Investment Bank and Wells Fargo will reportedly serve as lead underwriters.

Concert Pharmaceuticals focuses on applying its DCE Platform® (deuterated chemical entity platform) to create "novel, small molecule drugs" in an approach that "starts with approved drugs, advanced clinical candidates or previously studied compounds that can be improved with deuterium substitution to enhance clinical safety, tolerability and efficacy." *See BizJournals.com*, January 14, 2014; and *Concert Pharmaceuticals Inc. News Release*, January 23, 2014.

Achaogen Plans to Raise $75 Million in IPO to Develop Treatment for Bacterial MDR

South San Francisco-based biopharmaceutical company Achaogen, Inc. has filed an initial public offering (IPO) seeking $75 million to fund the development of lead drug plazomicin to treat multi-drug resistant (MDR) bacterial infections caused by a family of gram-negative bacteria including *Salmonella*. The company has, to date, been supported by Venrock, 5AM Ventures, Versant Ventures, Alta Partners, Arch Venture Partners, Domain Partners, Omega Funds, Frazier Healthcare Ventures, and the Wellcome Trust. In a January 24, 2014, filing with the U.S. Securities and Exchange Commission, the company lists as underwriters Credit Suisse, Cowen & Co., William Blair, and Needham & Co. *See San Francisco Business Times*, January 24, 2014.

BUSINESS CLIMATE

Biosimilar Development Costs May Affect Savings Potential

According to *Pharm Exec* Senior Editor Ben Comer, the biosimilars that were supposed to save consumers and taxpayers money as "the first wave of biologics" went off patent are unlike generic drugs because they take so long to develop and involve costly manufacturing and clinical trials—some seven to eight years in development with costs of up to $250 million. He suggests that with the biosimilars market expected "to climb to nearly $20 billion by 2018, it seems unlikely that health systems, in the U.S. and elsewhere, will see a dramatic decline in the overall cost of prescription drugs due to biosimilars." *See PharmExec.com*, January 21, 2014.

Ontario Pledges Funds for Research Programs and Infrastructure

Ontario's Ministry of Research & Innovation will reportedly invest CAN$190 million (US$173 million) during the next six years in research programs and infrastructure to help the province's institutions fund new technologies, attract and retain researchers, increase investment, and create new jobs. The investment will be handled by the Ontario Research Fund through its Research Infrastructure and Research Excellence programs. The latter program has reportedly supported 23,000 opportunities since 2003 for researchers to enhance their knowledge and skills and has been responsible for 64 spin-off companies that employ 571 people. An association of Ontario's hospitals and research institutes welcomed the announcement, estimating that every dollar from the fund represented three dollars of investment in the province, "including support from other partners and private industry." *See Council of Academic Hospitals of Ontario Media Release*, January 20, 2014; *University of Toronto News* and *Genomeweb.com*, January 21, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

India-Based Company's Drugs Barred from U.S. Market

The U.S. Food and Drug Administration (FDA) has prohibited imported drug products from a Ranbaxy Laboratories, Inc. facility in India due to violations of good manufacturing practices. Workers at the company's Toansa plant apparently retested raw materials, intermediate drug products and finished active pharmaceutical ingredients (APIs) until they achieved "acceptable" results. According to a news source, this is the sixth Ranbaxy facility that has failed to use good manufacturing practices.

Under a January 23, 2014, order based on a consent decree of permanent injunction entered against Ranbaxy in January 2012, the facility is barred from producing APIs for any U.S. pharmaceuticals until a third-party, independent expert satisfies FDA that good manufacturing practices have been met. FDA has indicated that it "is evaluating potential drug shortage issues that may result from this action." If a medically necessary drug is at risk of shortage, "the FDA may modify this order to preserve patient access to drugs manufactured under controls that are sufficient to assure quality, safety and effectiveness." *See FDA News Release* and *Law360,* January 23, 2014.

FDA Research Shows Device PAS Studies Lack Sufficient Numbers of Women

According to a study conducted by researchers with the U.S. Food and Drug Administration's (FDA's) Center for Devices and Radiologic Health, post-approval studies (PAS) of medical devices fail to include sufficient numbers of female participants. **Ellen Pinnow, et al., "Enrollment and Monitoring of Women in Post-Approval Studies for Medical Devices Mandated by the Food and Drug Administration," *Journal of Women's Health*, January 2014**.

Noting that FDA "has identified the importance of female participation in medical device trials and adequate representation of populations most likely to use a medical device" and has instituted policies to promote women's participation, the authors report nonetheless that women's PAS participation was not systematically tracked until recently. FDA will continue to work with "applicants to develop PAS that enroll and retain proportions of women that are consistent with the sex-specific prevalence for the disease or condition the device is used to treat" and will include sex-specific information when updating medical-device labels with information on health and safety benefits and risks.

LITIGATION

New York AG Settles with Patent Assertion Entity

New York Attorney General (AG) Eric Schneiderman has **entered** an agreement with MPHJ Technology, a patent assertion entity (PAE) operated by Texas attorney Max Rust. The agreement provides exemplars of the letters this PAE may use when informing New York businesses that they are infringing MPHJ patents and must obtain a license for their use or face litigation. The letters must be signed by the company and Rust rather than by any of its subsidiaries, may not contain a cash demand or boasts about positive responses from other businesses, and may not use the word "lawsuit." Under the agreement, MPHJ must also refund any New York business that paid for a license. *See NY AG Eric Scheiderman Press Release*, January 14, 2014.

Meanwhile, MPHJ has filed a complaint against the Federal Trade Commission (FTC) in a Texas federal court seeking to forestall threatened litigation by the agency over its "lawful, proper, and constitutionally protected efforts . . . to identify and seek redress for infringement of its U.S. patents." ***MPHJ Tech. Investments, LLC v. FTC*, No. 14-0011 (W.D. Tex., filed Jan. 13, 2014)**. According to the complaint, which seeks declaratory and injunctive relief under the First Amendment, "FTC's threatened suit is principally based upon the FTC's contention that if any U.S. patent owner threatens suit for infringement, even against a single infringer, and then fails promptly to bring suit for infringement, then that U.S. patent owner has committed an unfair trade practice under Section 5 of the FTC Act unless the patent owner bears the burden and can prove that at the time the threat was made, it intended to bring suit."

According to a news source, the complaint's attached exhibits reveal how MPHJ organized its 101 subsidiaries—bearing six-letter names such as GosNel and IntPar, discloses the number of MPHJ's targets and how they were chosen, and attaches FTC's draft complaint, which "reveals the mystery of who actually owns MPHJ . . . Jay Mac Rust, a Texas lawyer with a trail of troubled cases, including one where he was accused of running a 'Ponzi scheme.'" *See Ars Technica*, January 14, 2014.

Class Action Filed Against 23andMe, Inc. over Efficacy of Home DNA Test Kits

A New Mexico resident has filed a putative nationwide class action against 23andMe, Inc., alleging that claims for its DNA Collection Kits—advertised as useful in providing accurate information about "genetic predisposition to a range of health factors such as coronary artery disease and arthritis"—are unsubstantiated, not based on scientific testing and unauthorized by the U.S Food and Drug Administration (FDA). *Stanton*

v. 23andMe, Inc., No. 14-0294 (U.S. Dist. Ct., N.D. Cal., filed January 15, 2014). Information about similar litigation filed against the company in December 2013 appears in Issue 69 of this *Bulletin*.

The complaint relies on an FDA warning letter informing the company that it had violated the Federal Food, Drug, and Cosmetic Act by failing to seek the agency's approval before marketing its DNA-analysis service. Details about the warning letter also appear in Issue 69. According to the plaintiff, FDA expressed doubts in its letter "about whether the PGS [personal genome service] tests, especially the tests associated with the Health Kit, performed as 23 warranted that they did. The FDA also said that it was concerned about the public danger surrounding false positives and negatives for serious health conditions purportedly tested by the Health Kit." Also included in the complaint are purportedly negative consumer product reviews. The plaintiff alleges violations of California's False Advertising Law, Unfair Competition Law and Consumers Legal Remedies Act; negligent misrepresentation; unjust enrichment; breach of warranty of merchantability and fitness for a particular purpose; and deceit by concealment. He seeks injunctive relief; restitution; actual, statutory and punitive damages; attorney's fees; costs; and interest.

NEWS BYTES

The U.S. Food and Drug Administration **issues** draft guidance titled "Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)" to address the proper collection, storage and manufacture of animal-derived materials that could pose a risk of infectious disease transmission. Comments are requested by April 23, 2014.

The U.S. Food and Drug Administration (FDA) **announces** that its collection of information titled "Investigational New Drug Safety Reporting Requirements for Human Drugs and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans" has been approved by the Office of Management and Budget. The approval expires December 31, 2016.

The U.S. Food and Drug Administration (FDA) **issues** draft guidance titled "Guidance for Industry Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics." Intended to address how drug manufacturers can properly promote their products on social media such as "blogs, microblogs, social networking sites, online communities, and live podcasts," the document discusses, among other things, when manufacturers are responsible for the content of promotional material and how such communications should be provided to regulators for review. It also

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covers the circumstances under which a manufacturer is responsible for promotional content and is thus required to submit that material to FDA. Comments are requested by April 14, 2014.

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