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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
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FIRM NEWS

Strand Authors Article on Federal Circuit's "At War" Standard

Shook, Hardy & Bacon Intellectual Property Partner **Peter Strand** has authored an article titled "Startling Jurisdiction Expansion?—'At War' Standard Modifies 'Case-or-Controversy' Requirement," appearing in the July 2014 issue of Walters Kluwer's *Intellectual Property & Technology Law Journal*. The article discusses the Article III case-or-controversy standard applied to patent infringement lawsuits before the Federal Circuit Court of Appeals decided *Danisco U.S. Inc. v. Novozymes A/S,* which appears to have redefined and expanded the Article III jurisdiction standard in a declaratory judgment action.

The court concluded that the record demonstrated the existence of a definite and concrete patent dispute between the parties, stating that they "have plainly been at war over patents involving . . . enzymes and are likely to be for the foreseeable future." In this regard, the court rejected the defendant's argument that Article III was not satisfied because Danisco's declaratory judgment claims were based on "nothing more than speculation and a subjective fear of Novozymes's purported enforcement of its patent rights."

Strand suggests that the ruling "could be practice changing. The old 'reasonable-apprehension-of-suit' test apparently has given way to a new, much more liberal, 'at war' standard." He concludes by setting forth the questions counsel should ask when evaluating whether this "new-found tool for infringement cases between competitors" can be applied in their disputes.

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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IP NEWS

IG Report Finds $5 Million in Waste and Mismanagement at USPTO

The U.S. Department of Commerce Office of Inspector General (IG) has issued a report after receiving anonymous whistleblower complaints alleging that certain U.S. Patent and Trademark Office (USPTO) employees were being paid for not working. According to the IG's investigation, "substantial, pervasive waste" at USPTO's Patent Trial and Appeal Board "endured for more than four years and resulted in the misuse of federal resources totaling at least $5.09 million." Apparently, a number of paralegal specialists were hired in early 2009 to address a growing backlog of appeals, but because only one judge was hired before a hiring freeze was instituted, many of the paralegals had "insufficient work to fill a full-time work schedule" and, working from home, filled their time instead with personal activities such as surfing the Internet, doing laundry, reading books, and shopping online. The report indicates that the employees' managers were aware of the waste and even rewarded these paralegals with performance bonuses. Among other matters, the IG recommends better oversight, "clearer telework rules" and training.

INVESTOR NEWS

Sage IPO Brings Greater than Expected Returns

Cambridge, Massachusetts-based biopharmaceutical Sage Therapeutics reportedly raised $90 million in its initial public offering (IPO), which was expected to raise about $60 million when first announced. The IPO closed with the sale of 5.75 million shares of common stock at a price of $18 per share, before underwriting discounts that included the exercise in full by underwriters of an option to purchase an additional 750,000 shares. The company, which focuses on central nervous system disorders, plans to use $10 million of the proceeds to fund a Phase I/II study of SAGE-547, its therapeutic for super-refractory status epilepticus (SE), a rare seizure condition with no approved treatments. Another $10 million will be used to fund the development of SAGE-689 for the treatment of adjunctive SE, and $7 million will go toward SAGE-217, an SE maintenance therapeutic.

Biotechnology companies have apparently experienced mixed results on Wall Street following a record-setting first quarter that reportedly brought in $2.1 billion in IPOs. Other biotechs have not fared as well as Sage, with some delaying, discounting or terminating their debuts due to unfavorable market conditions. Still, some companies with what are viewed as "promising assets" have moved forward with good results. For example, Kite Pharma raised $128 million in a June 2014 IPO to develop cancer

immunotherapies, Zafgen, Inc. raised $96 million to support a promising obesity treatment, and Ardelyx raised $60 million to develop drugs that treat inflammatory bowel disease. *See FierceBiotech*, July 18, 2014; *Sage Therapeutics News Release*, July 23, 2014.

Epic Sciences Completes $30 Million Series C Financing for Novel Cancer Diagnostics

Biotechnology company Epic Sciences, Inc., which develops novel diagnostics to personalize the treatment and management of cancer, has reportedly raised $30 million in a Series C financing round that included new investors RusnanoMedInvest and Arcus Ventures, as well as existing investors. The San Diego, California-based biotech will use the proceeds to "commercialize its circulating rare cell analysis platform with special focus on developing products and services to detect circulating tumor cells (CTC) in cancer." According to the company, its technology enables minimally invasive characterization of protein biomarker and genomic profiles in CTCs thus allowing for optimum therapy selection and the early detection of drug resistance. Epic has apparently established some 30 partnerships with leading pharmaceutical companies and cancer centers that have used its technology to analyze a broad array of cancers in thousands of patients. *See xconomy.com* and *Epic Sciences, Inc. Press Release,* July 30, 2014.

Eye Disease Treatment Co. Shares Soar to $102 Million in IPO

Avalanche Biotechnologies, Inc., which raised its targets twice before the eye-disease treatment company's initial public offering (IPO) closed, reportedly hit the top of its range, selling 6 million shares for $17 each and closing up 65 percent at $27.99. Jeffries LLC, Cowen & Co., LLC and Piper Jaffray & Co. acted as joint book-running managers, and William Blair & Co., L.L.C. acted as co-manager for the offering. Headquartered in Menlo Park, California, the clinical-stage biotechnology company focuses on discovering and developing novel gene therapies for sight-threatening ophthalmic diseases. Its platform technology is adeno-associated virus-based, and lead product AVA-101 is in a Phase 2a trial for wet age-related macular degeneration. *See Avalanche Biotechnologies, Inc. News Release* and *Silicon Valley Business Journal*, July 31, 2014.

IPO Generates $68 Million for Targeted Cancer Therapy Development

Biopharmaceutical company Loxo Oncology, Inc. reportedly raised $68 million in an up-sized initial public offering (IPO), selling 5.3 million shares at $13—the middle of its expected range. With nearly 790,000 shares

set aside for overallotments and a 230,729-share private placement with existing investor New Enterprise Associates, the maximum deal value could reach more than $81 million. The company develops targeted cancer therapies for genetically defined populations; its lead drug, LOXO-101, a TRK-blocking compound, is currently in Phase I development. The Stamford, Connecticut, firm believes the drug has potential in brain, lung, thyroid, and breast cancers. *See Loxo Oncology, Inc. News Release* and *FierceBiotech*, August 1, 2014.

Synlogic to Use $29.4 Million Series A Financing to Develop Therapeutic Microbes

Synlogic, Inc. has reportedly raised $29.4 million in a Series A financing round led by Atlas Venture and New Enterprise Associates. The Cambridge, Massachusetts-based biotech focuses on developing therapeutic microbes that sense physiologic conditions, perform a therapeutic function and deactivate when done. According to Synlogic Chair Peter Barrett, "The unique features of the Synlogic platform enable us to develop high potential therapeutics today; in addition, the evolving understanding of the microbiome creates opportunities for us to apply the platform to create novel therapeutics for many years into the future." The company was founded in fall 2013. *See Business Wire*, July 22, 2014.

NIH Awards 23andMe $1.4 Million Grant to Build Web-Based Database

The National Institutes of Health (NIH) has awarded a $1.4 million two-year grant to personal genome service company 23andMe. The grant is intended to help the company enhance its survey tools and expand its gene database. Among other matters, the grant will be used for web-based survey refinements designed to improve the company's ability to identify novel genetic associations and support the collection of a broader set of phenotypic data to improve survey usability. 23andMe will also use data from large public and internal sequencing projects, aiming to discover rarer, more penetrant genetic associations. The company's external researchers will also be able to access aggregated de-identified data from its database to accelerate the pace of human genetic research. According to a news source, the project will lead to a database with genotypes for 40 million single nucleotide polymorphisms, as well as information on thousands of diseases and traits for more than 400,000 individuals. *See Reuters* and *GenomeWeb*, July 29, 2014.

Meanwhile, *FierceBiotech* has analyzed NIH funding data to determine the disorders and diseases that the U.S. government has apparently prioritized. With a current budget of $30.1 billion, NIH is the single largest funder of biomedical research in the world. Although funding was slashed

nearly across the board in 2013 due to sequestration and automatic spending cuts that have been instituted in the absence of congressional budgetary compromise, the top disease areas by amount of funding since fiscal year 2012 are cancer, infectious diseases, brain disorders, rare diseases, pediatric disorders, HIV/AIDS, aging, mental health, cardio-vascular, emerging infectious diseases, neurodegenerative, digestive disorders, heart disease, lung disease, and hematologic diseases. *See FierceBiotech Research*, July 22, 104.

BUSINESS CLIMATE

Corporate Venture Funding for Biotechs Surges

Silicon Valley Bank (SVB) has **issued** a report that explores health-care and biotech investments and exits based on 2013 data and concludes, "Large biopharma companies are essentially outsourcing early-stage R&D by investing heavily in young venture-backed companies and as significant investors into Healthcare Venture funds. Among big M&A exits (defined as private, venture-backed M&A with upfront payments of $75 million or higher for biopharma deals and $50 million or higher for device deals): The average total deal value for biopharma big exit M&A was $549 million in 2013, the highest level since SVB started tracking the data in 2005, and it represents a 10 percent increase over 2012. Device big exit M&A activity declined, but the average total deal value was $231 million in 2013, a three-year high, which represents a 42 percent increase over 2012." Noting that 2013 was the year of the initial public offering (IPO), SVB analysts predict "healthy access to capital in 2014 and into 2015. While IPO activity is cooling in these sectors, we expect to see an increase in big exit M&A activity in the second half of the year." *See Silicon Valley Bank News Release*, July 30, 2014.

Analysts Predicts Biosimilars Boom as Biologics Reach New Patent Cliff

A new Allied Market Research (AMR) report predicts that the global biosimilars market, which accounted for $1.3 billion in 2013, will generate $35 billion by 2020, driven in large part by the expiration of "most of the blockbuster patents" over the next four years—a new patent cliff. Because the EU's stringent biosimilar regulations are considered the world's benchmark and were the first to be drafted, the European market is ahead of other regions in developing these products. Still, the report notes, "Biosimilars developers have been using emerging markets with less intel-lectual property protection as their launch pad for established markets. With regulatory framework maturing in established markets, it will be easier for biosimilar manufacturers to quickly enter into such markets." *See FierceBiotech*, July 22, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

U.S. Senators Call on FDA to Finalize Biosimilars Guidance

Five Republican U.S. senators have **written** to Health and Human Services (HHS) Secretary Sylvia Burwell to express concerns about the Food and Drug Administration's (FDA) failure to date to issue guidance on the pathway to compliance for biosimilars, including "the key scientific policy questions related to biosimilars, such as naming, labeling, indication extrapolation, and interchangeability."

According to Sen. Orrin Hatch (R-Utah), who, with Sen. Lamar Alexander (R-Tenn.), led their colleagues in calling on the administration to release biosimilar drug approval guidance documents, FDA has just accepted its first biosimilar application for review. They ask whether the agency intends "to approve the first biosimilar before policies on these key scientific questions are publicly released." The letter indicates that FDA has forwarded the naming guidance to HHS, "and this guidance is awaiting HHS' clearance so it can be released for stakeholder comment. . . . We urge you and those within your Department to immediately release guidance pending within the HHS related to the implementation of the biosimilar pathway."

Meanwhile, FDA has **announced** the rates for biosimilar user fees for fiscal year 2015 (October 1, 2014, through September 30, 2015). The fee rate for initial biological product development (BPD) is $233,520; the annual BPD fee, assessed for the product each fiscal year until the sponsor submits a marketing application that is accepted for filing, or discontinues participation in FDA's BPD program, is the same. The reactivation fee is nearly $500,000, and an application requiring clinical data is $2.33 million, while an application not requiring clinical data is $1.16 million. If the sponsor has submitted BPD and/or reactivation fees, the application fee is reduced accordingly. *See Sen. Orrin Hatch Press Release* and *Federal Register*, August 1, 2014.

FDA has also **issued** draft guidance for industry titled "Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act." According to the agency, the document "is intended to assist sponsors developing biological products, sponsors holding biologics license applications (BLAs), and other interested parties in providing information and data that will help the Agency determine the date of first licensure for a reference product under 351(k)(7)(C) of the Public Health Service Act (PHS Act), as added by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The BPCI Act amends the PHS Act and other statutes to create an abbreviated licensure pathway for biological products shown to

be biosimilar to, or interchangeable with, an FDA-licensed biological reference product." Comments are requested by October 6, 2014. *See Federal Register*, August 5, 2014.

FDA Increases Drug Facility Fees

The U.S. Food and Drug Administration (FDA) has **established** fiscal year 2015 drug facility user fees that have increased 12-15 percent over current rates. The new fees will take effect October 1, 2014. Facilities in India, which is the largest source of medicines to the United States, will pay more than domestic facilities. According to a news source, India currently has 150 FDA-approved plants. A foreign finished dosage form (FDF) facility will pay $262,717 compared to a domestic FDF, which will pay $247,717. A foreign active pharmaceutical ingredient facility (API) will pay $56,926, and a domestic API facility will pay $41,926. Some user-fee rates have fallen; for example, the new fee for drug master files is $26,720, down 15 percent from the previous year, and the rates for abbreviated new drug applications have been lowered some 8 percent to $58,730. *See Federal Register*, August 1, 2014; *livemint.com*, August 3, 2014.

LITIGATION

23andMe Insurer Claims no Duty to Defend Company

The insurance carrier that issued a "Products/Completed Operations Liability and Professional Liability Policy for Life Sciences" policy to 23andMe, Inc., a company that sold personal genome services to consumers, has filed a declaratory judgment action against its insured claiming that it has no duty to defend or indemnify 23andMe "(1) in lawsuits and arbitrations where the underlying plaintiffs seek restitution, disgorgement and other forms of relief that are not insurable under the Policy or the law, and; (2) with respect to a Civil Investigative Demand, [instituted by the Washington attorney general] which does not qualify as a Claim under the Policy." *Ironshore Specialty Ins. Co. v. 23andMe, Inc.*, No. 14-3286 (U.S. Dist. Ct., N.D. Cal., filed July 21, 2014).

According to the complaint, the insurance carrier has agreed to defend 23andMe in certain actions under a reservation of rights and further allowed the company to retain independent counsel who would be paid reasonable attorney's fees. The complaint alleges that counsel has "submitted bills to Ironshore that seek payment of excessive and unreasonable attorney's fees and costs, as well as attorney's fees and costs that are not covered under the provisions of the Policy." While the parties have apparently continued to discuss coverage issues, in the interim, the underlying plaintiffs have allegedly made a settlement demand that 23andMe "contends is covered by the

Ironshore Policy." Setting forth a number of policy provisions, the carrier claims that it has no duty to defend or indemnify under several exclusions and because the underlying actions do not qualify under definitions for damages and claims.

Further details about a court order sending a number of the underlying complaints to arbitration appear in Issue **81** of this *Bulletin*. The underlying plaintiffs allege that 23andMe falsely marketed the home DNA test kits and results as useful in diagnosing health conditions and preventing disease, when the results were actually inaccurate and incomplete and the product and service had not been approved by the U.S. Food and Drug Administration. They also apparently allege that the company "plans to use the genetic information it gathers about its customers to create a database that 23andMe can later market to physicians and pharmaceutical companies" and failed to adequately disclose these plans to consumers. Alleging economic injury, they seek return of the fees paid and disgorgement of profits.

EU Court of Justice Advocate General Issues Ruling on Stem Cell Patentability

In a non-binding **ruling**, Advocate General Cruz Villalón of the EU Court of Justice has determined that unfertilized human ova whose division and further development have been stimulated by parthenogenesis are not within the term "human embryos" in Article 6(2)(c) of Directive 98/44/EC on the legal protection of biotechnological inventions "as long as they are not capable of developing into a human being and have not been genetically manipulated to acquire such a capacity." *Int'l Stem Cell Corp. v. Comptroller Gen. of Patents*, Case C-364/13 (E.C.J. Advocate Gen., decided July 17, 2014). The case had been referred from the High Court of Justice of England and Wales on an appeal from the U.K. Intellectual Property Office's determination that the International Stem Cell Corp. could not patent methods of producing pluripotent human stem cell lines from parthenogenetically-activated oocytes (referred to as parthenotes), as well as stem cell lines produced by these methods.

The advocate general reached his conclusion by finding that the judgment in *Brüstle,* C-34/10, EU:C:2011:669, did not require a contrary result. According to his ruling, the court believed in 2011 that fertilized ova, parthenotes and non-fertilized ova subjected to somatic-cell nuclear transfer were functionally equivalent, because the science at the time and the record before the court did not clarify that parthenotes cannot, without further manipulation, develop into human beings—they simply develop into the blastocyst phase from which pluripotent but not totipotent stem cells can be derived. The advocate general found the distinction significant and described how totipotent cells are capable of developing

into all human cell types including extra-embryonic tissue and into a complete human being, but that pluripotent cells "can develop into all cells that make up the body, but not into extra-embryonic tissue and hence cannot develop into a human being."

The opinion also considers how the Directive "opens up a space for ethical and moral considerations under the categories of *ordre public* and morality, a space that is particularly pronounced when it comes to biotechnology relating to the species *homo sapiens*." In this regard, the advocate general states that each member state may determine which inventions are not patentable in light of considerations of *ordre public* and morality, but that the Directive "establishes a nucleus of non-patentability, a kind of 'no-go zone' that is common for all Member States as an expression of what has to be considered unpatentable in any case." In this category are human embryos. By defining parthenotes not subject to further manipulation as not within the definition of "human embryos," the advocate general removed them from this unpatentable baseline.

Several countries participated in the proceedings and advanced a similar position, although Poland argued that "in the interest of safeguarding human dignity the [*Brüstle*] Court correctly relies on the capacity of *commencing* the process of development of a human being." Because parthenotes "initially undergo the same stages of development as a fertilised ovum, namely cell division and differentiation," Poland argued that they thus "constitute human embryos." The advocate general disagreed, saying "the mere possibility of a posterior genetic manipulation altering the fundamental characteristics of a parthenote does not change the parthenote's character *before* the manipulation."

NEWS BYTES

The U.S. Patent & Trademark Office (USPTO) **selects** 19 law schools to join its Law School Clinic Certification Pilot Program. Four of the law schools will join five others already participating in a clinical program that provides *pro bono* patent legal services to independent inventors and small businesses. Clients can expect through the program to receive professor-supervised searches and opinions, advice about IP needs, application drafting and filing, and representation before USPTO.

The U.S. Food and Drug Administration (FDA) **schedules** a September 5, 2014, public meeting "to discuss current scientific and regulatory approaches to biomarker development, acceptance, and utility in drug and biologic development programs." A live Webcast of the meeting will be available and can be viewed for one year on the Website of FDA collab-

orator the Brookings Institution. Comments are requested by November 5. The meeting will specifically focus on "identifying challenges for biomarker applications in early- and late-phase clinical trials and emerging best practices for successful biomarker-based programs, including codevelopment of in vitro diagnostic devices and use of biomarkers as outcome measures in clinical trials."

The U.S. Food and Drug Administration (FDA) **issues** guidance for industry and staff titled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]." The document describes the agency's "current review practices for premarket notification submissions [for medical devices] by describing in greater detail the regulatory framework, policies, and practices underlying FDA's review of traditional 510(k) submissions." Comments on the guidance may be submitted at any time.

The U.S. Food and Drug Administration **establishes** a public docket as part of an initiative related to reserving proprietary names for drug products once the agency has "tentatively accepted" a proposed proprietary name. Stakeholders have apparently expressed concerns that the existing process for reserving names does not provide applicants with sufficient certainty before application approval that a proposed proprietary name will be included in approved drug labeling. New drug names can be rejected if they are likely to contribute to medication error or otherwise render the drug misbranded or if an intervening product approval involves a confusingly similar name. As to the latter, the agency may not be able to disclose certain information to applicants about other pending applications. Comments on these and related issues are requested by October 27, 2014.

The U.S. Food and Drug Administration (FDA) **seeks** public comments on the estimated time burdens relating to the extension of an existing information collection pertaining to the recalls of all FDA-regulated products (including food, animal feed, drugs, animal drugs, medical devices, cosmetics, biological products intended for human use, and tobacco). The estimates are based on the total number of recalls from 2011 to 2013 (11,403) averaged to 3,801 per year and involve the time burdens of complying with the voluntary reporting requirements of the agency's recall regulations. Comments must be submitted by October 3, 2014.

Shook, Hardy & Bacon L.L.P.

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The U.S. Food and Drug Administration **announces** the submission to the Office of Management and Budget of a proposed collection of information relating to a study of more than 6,000 adolescents, young adults and their parents to assess direct-to-consumer drug marketing to adolescents and how adolescents weigh risks and benefits. The agency included in the notice information about the estimated time burdens of the proposed surveys and its responses to comments from stakeholders when it previously announced the proposed experimental study. The questionnaire is available on request.

The U.S. Food and Drug Administration **requests** public comment on the estimated time burdens related to the extension of an existing information collection "associated with the medical device labeling regulations" as to certain products, including latex condoms, menstrual tampons, contact lens cleaning solution, impact resistant lenses, and sunlamp products. Comments are requested by September 30, 2014.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

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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