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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

New Patent Trial and Appeal Board Becomes Strategic Venue of Choice

According to a news source, companies hoping to prevail in patent-infringement lawsuits have turned with increasing frequency to the Patent Trial and Appeal Board, which, created under the America Invents Act, first opened its doors in September 2012. The board considers patent-validity challenges and functions under an accelerated resolution deadline—one year for most petitions granted and 18 months under extraordinary circumstances—which is apparently less than half the time on average for a patent dispute to go to trial in the federal district courts. Companies have filed 650 patent-validity challenges during the board's first year of operation, making it a venue that rivals the Eastern District of Texas, where more than 1,200 new patent cases were filed over the same time period.

With 182 judges and 50 more expected to be hired, the board is not required to hear every case, just those in which the petitioner can show it is "more likely than not" to prevail. It has apparently turned down few challenges to date under the standard. The board's attraction for companies embroiled in patent-infringement litigation is the possibility that a pending Patent Trial and Appeal Board proceeding will support a motion to stay in district court, viewed as "a huge money saver." For example, in one recent dispute over motor vehicle sensors, the district court agreed to enter a stay in the infringement proceeding, finding that it would be "wasteful to now engage in litigation over patent claims that are likely to be altered or invalidated." *See The National Law Journal*, October 21, 2013.

WSJ Points to America Invents Act Scrivener's Error on Post-Grant Review Procedure

While some business interests are apparently willing to use the new post-grant review procedures before the U.S. Patent and Trademark Office (USPTO) as a cost-effective means to delay patent-infringement litigation in which they are embroiled, others have reportedly expressed concerns over an America Invents Act provision that purportedly expanded the

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law's originally intended estoppel effect. Under the current version, a post-grant review proceeding estops the petitioner from arguing in other forums "any ground that the petitioner raised or reasonably could have raised during that post-grant review." 35 U.S.C. § 325(e). Congress reportedly intended the law to stop a party challenging a patent's validity within nine months of its issuance or reissuance before USPTO's Patent Trial and Appeal Board from raising the same arguments later when challenging its validity in court. A new patent-law reform bill, discussed elsewhere in this *Bulletin*, will address those concerns and narrow estoppel to the grounds actually raised. Until it is changed, however, some contend that the nine-month window for filing a post-grant challenge is not sufficient to decide all grounds that "reasonably could have been raised." *See The Wall Street Journal (WSJ)*, October 27, 2013.

INVESTOR NEWS

Biotech Raises $32 Million and Signs Agreement with Global Pharmaceutical Co.

Boston-based Sideris Pharmaceuticals, Inc., which develops therapies to treat transfusion-related iron overload, has completed a $32-million Series A equity financing round. MPM Capital led the round with participation from Hatteras Venture Partners and Osage University Partners. Sideris has also inked an agreement with Novartis Pharmaceuticals, granting the Swiss drug-maker the exclusive right to acquire Sideris and its lead asset, iron-chelating drug candidate SP-420. Including upfront, acquisition and milestone payments, the agreement with Novartis could reportedly reach up to $300 million.

According to a company news statement, the combination of the Novartis agreement and the closing of the Series A financing will allow Sideris to "advance the SP-420 program through a large Phase 2 clinical study in transfusion-related iron overload." *See Sideris Pharmaceuticals, Inc. News Release*, October, 22, 2013.

Veracyte Increases IPO Target to $81 Million

South San Francisco-based Veracyte, Inc., which earlier this year completed a $28-million Series C financing round to expand and roll out its thyroid nodule test, has filed an amended registration statement with the U.S. Securities and Exchange Commission indicating its intent to raise more than $81 million in an initial public offering (IPO) of 5.4 million shares of common stock. Information about the company's financing round appears in Issue 60 of this *Bulletin*. The company's initial filing estimated the IPO at $74.7 million. Veracyte focuses on molecular

cytology solutions to help physicians reduce unnecessary surgeries by making more informed decisions at earlier stages in a patient's treatment. Morgan Stanley & Co. and Leerink Swann are listed as joint book-running managers for the public offering. *See Veracyte, Inc. Press Release*, September 20, 2013; *Veracyte Form S-1 Amended Registration Statement*, October 17, 2013.

Oxford Immunotec Prices IPO Above $86 Million

Oxford Immunotec Global PLC has filed an amended registration statement with the U.S. Securities and Exchange Commission to raise approximately $86 million in an initial public offering (IPO). The Abingdon, United Kingdom-based medical-diagnostics company, with North American headquarters in Marlborough, Massachusetts, reportedly had $29 million in sales for the 12-month period ending June 30, 2013, from its new cellular blood test for the detection of active and latent tuberculosis infection. The company describes its T-SPOT® technology as "a simple and accurate method of measuring a person's immune response to infection." *See Oxford Immunotec Global Form S-1 Amended Registration Statement*, October 25, 2013.

BUSINESS CLIMATE

Major Life Science Biotechs Cluster in Boston Region

Xconomy's Luke Timmerman has compiled information on biotech companies with at least $100 million in cash—"members of the $100 million club"—to compare the biotech hubs on which this media outlet focuses. He also collected data from 2003 to understand which regions are gaining in this industrial sector and which may be losing. Timmerman was apparently surprised to find that Boston has become a clear leader, growing in 10 years from hosting 12 qualifying companies to 35. San Francisco was a respectable second, growing from 19 biotechs in 2003 to 24 today. On the other hand, Seattle has apparently lost ground, dropping from five members of the club to two today.

According to Seattle-based Timmerman, "it's been painful to watch. . . . Local officials won't admit in public that there's a problem, and as far as I can tell, they still seem to think if they repeat everything's great, people will believe it. But they ought to be paying attention to this disturbing trend. If things are so great, then why are skilled biotech workers finding it so tough to finds jobs here? Why aren't more exciting companies getting started?" *See Xconomy.com*, October 14, 2013.

Growth of 'Bio-Factories' Expected to Increase

According to *The Washington Post*, annual revenue from companies that manufacture industrial chemicals through synthetic biology is approximately $1.5 billion and will increase at a rate of 15 to 25 percent per year during the next few years. One such company, Emeryville, California-based Amyris, is reportedly creating new organisms—mostly forms of genetically modified yeast—at the rate of more than 1,500 a day. Some of these organisms convert sugar into medicines. Others create moisturizers that can be used in cosmetics. And others make biofuel, a renewable energy source, usually made from corn.

In early 2013, Amyris began to market laboratory-grown artemisinin, an herbal remedy found to be more than 90-percent effective at curing those infected with malaria. A vanilla flavoring, reported to cost far less than the extract made from beans, is scheduled for introduction in 2014. "You can now build a cell the same way you might build an app for your iPhone," Amyris Chief Science Officer Jack Newman reportedly said.

Proponents claim that this kind of work marks the beginning of a third industrial revolution—one based on using living systems as "bio-factories" for creating substances that are either too complex or expensive to grow in nature or to make with petrochemicals, states the *Post* article. Although the rush to biological means of production may revolutionize the chemical industry and transform the economy, it also raises questions about environmental safety and biosecurity and encourages ethical debates about "playing God," according to author Ariana Eunjung Cha.

Other applications evidently under study include (i) biosensors that light up when a parasite is detected in water, (ii) goats with spider genes for the production of super-strength silk in their milk, and (iii) synthetic bacteria that can quickly decompose trash and break down oil spills and other contaminated waste. *See The Washington Post,* October 25, 2013.

United States Leads World in Advanced Biofuel Ventures

Navigant Research reports in "Advanced Biofuels Country Rankings" that the United States is currently home to some two-thirds of the world's advanced biofuels ventures. According to Navigant research analyst Mackinnon Lawrence, "[T]he Renewable Fuel Standard, which calls for 21 billion gallons of advanced biofuel production by 2022, will help keep the U.S. at the epicenter of the market going forward." Advanced biofuels, derived from food waste, algae and non-food materials, are under development throughout the world to replace fossil fuels. While Navigant predicts that growth in the industry will slow through 2015, as peaks in government funding and investments fall, another round of rapid growth is anticipated thereafter, with existing facilities expanding and retrofitting. The report

considers "the potential for global advanced biofuels products based on four assessment frameworks: liquid fuel demand, feedstock opportunity, market drivers, and market investment." *See Navigant Research Press Release*, October 15, 2013.

R&D for New Drugs to Treat "Neglected Diseases" Continues to Lag

European researchers writing in a medical journal have found that just 4 percent of new therapeutic products registered with drug regulatory authorities between 2000 and 2011 were for "neglected diseases," defined as malaria, tuberculosis, diarrhoeal diseases, neglected tropical diseases, and other diseases of poverty. Belen Pedrique, et al., "The drug and vaccine landscape for neglected diseases (2000-11): a systematic assessment," *The Lancet*, October 24, 2013. While an improvement over the 1.1 percent of drugs and vaccines targeting neglected diseases developed from 1975 to 1999, this is still, according to the authors, inadequate given that "these diseases accounting for 12% of the global health burden." The article also notes that of the new products, including vaccines and biologicals, "few are truly innovative: most are based on the repurposing of existing treatments, namely reformulations, new indications, or fixed-dose combinations." They attribute the state of research for neglected diseases to a preference for investing in "diseases with large volumes or a potential market." Although new private and public funding has recently increased the resources available for the research and development (R&D) of neglected disease therapeutics, such as contributions from the Bill & Melinda Gates Foundation, "in 2010 only 1% of research and development investment for global health was allocated to neglected diseases."

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Patent Lawsuit Reform Bill Garners Wide Support

A U.S. House bill titled the "Innovation Act" (**H.R. 3309**) has support from both sides of the political aisle and in the business community. Introduced on October 23, 2013, by Rep. Bob Goodlatte (R-Va.), the measure would, among other matters, correct technical errors in the America Invents Act; close certain gaps that purportedly enable abusive litigation, including enhanced pleading requirements for patent-infringement claims; require attorney fee-shifting in favor of the prevailing party; place limits on discovery; and reduce post-grant review estoppel from grounds that could have been raised during the proceeding to grounds actually raised.

During an October 29 Judiciary Committee **hearing**, former USPTO director David Kappos urged caution, contending that the ink had not

yet dried on the patent reform bill enacted two years ago. He reportedly said, "In such long-time constant situations, every engineering instinct and every leadership instinct tells me: Proceed with caution. By the time an overcorrection is apparent, it will be years after the system is badly damaged." Still, Goodlatte defended the proposal, insisting that it "goes to the heart of current abusive patent litigation practices. The patent system was never intended to be a playground for litigation extortion and frivolous claims." Others attending the standing-room-only hearing testified in support of the bill, with one corporate counsel saying that its "narrow focus" would "help reinstate the balance and transparency necessary to ensure that the U.S. remains the most innovative and competitive country in the world." *See The National Law Journal*, October 23 and 29, 2013.

Bipartisan Bill Would Curb FDA's Medical Apps Oversight

A bipartisan group of U.S representatives has introduced the Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act (**H.R. 3303**) that seeks to clarify rules for mobile medical applications (apps), clinical decision support, electronic health records, and other health care-related software. According to Rep. Marsha Blackburn (R-Tenn.), who introduced the measure, the legislation builds on guidance recently released by the Food and Drug Administration (FDA) and codifies its risk-based approach to provide "the regulatory certainty that technology companies need in order to continue to drive innovation and ensure patient safety."

Citing estimates indicating that the number of consumers who use medical apps on smart phones is expected to grow to 500 million by 2015, the bill's sponsors claim that FDA lacks the necessary tools to appropriately oversee these products without "overstepping their [sic] authority and stifling innovation." Under current law, FDA can use its definition of a medical device to assert "broad regulatory authority" over a wide array of software, said the legislators. "The SOFTWARE Act tailors [FDA] authority to the realities of the 21st century by focusing [it] onto the products that pose a potential risk to human health. "

If approved, the bill would create three classification levels of software—clinical, health and medical. FDA would retain authority over medical software, defined as technology intended to "change the structure or any function of the body" and to produce medical advice without the involvement of a doctor. The agency would be blocked, however, from overseeing "clinical software," which would include technology intended for use only by health care providers to analyze patient information without performing functions that alter the human body.

Lastly, regulators would be barred from policing "health software," which the bill defines as technology that "analyzes patient information, is not used in direct delivery of care, is primarily a platform for secondary software, or merely stores data." Reps. Gene Green (D-Texas), Phil Gingrey (R-Ga.), Diana DeGette (D-Colo.), Greg Walden (R-Ore.), and G. K. Butterfield (D-N.C.) co-sponsored the bill. *See Rep. Marsha Blackburn News Release*, October 22, 2013; *Law 360,* October 23, 2013.

Senators Query FDA on Biosimilar Naming Policy

A bipartisan group of U.S. senators has demanded to know why the U.S. Food and Drug Administration (FDA) has removed a 2006 statement on naming biologicals from its Website, concerned that the agency may be considering a change to its position. In the October 23, 2013, letter, Sens. Tom Harkin (D-Iowa), John McCain (R-Ariz.), Bill Nelson (D-Neb.), John Rockefeller IV (D-W.Va.), Charles Schumer (D-N.Y.), and Ron Wyden (D-Ore.) note the significance of naming biosimilars and assert, "If biosimilars are unable to share the same active ingredient name as the brand originator product, we believe the Congressional intent behind the BPCIA [Biologic Price Competition and Innovation Act] would be undermined as would the safety and accessibility of affordable biosimilars."

They also report that, while the matter was debated, Congress "ultimately rejected a statutory requirement that biosimilars be given unique INNs [International Nonproprietary Names]." They contend that such a requirement could "lead to patient and prescriber confusion, increasing the possibility of medication errors, [and] separate the biosimilar product from the existing safety data on the brand biologic, placing this important information beyond easy reference." They further contend that a unique name could "stand in the way of otherwise appropriate substitution" at the expense of cost savings and "would make U.S. product names different than those in the rest of the world, contrary to the policy of the WHO [World Health Organization] naming system."

USPTO Adopts Final Rule to Implement Patent Law Treaty Changes

The U.S. Patent and Trademark Office (USPTO) has **issued** a final rule to revise its procedures for consistency with changes in the Hague Agreement Concerning International Registration of Industrial Designs and the Patent Law Treaty in title II of the Patent Law Treaties Implementation Act of 2012 (PLTIA). Effective December 18, 2013, the rule does not include changes necessitated by the Hague Agreement and title I of the PLTIA; these will be implemented in a separate rulemaking.

Notable changes include (i) a patent application's filing date requirements, (ii) patent rights restoration "via the revival of abandoned application and

acceptance of delayed maintenance fee payments," (iii) "restoration of the right of priority to a foreign application or the benefit of a provisional application in a subsequent application filed within two months of the expiration of the twelve-month period (or six-month period for design applications) for filing such a subsequent application," and (iv) patent term adjustment provision revisions "to provide for a reduction of any patent term adjustment if an application is not in condition for examination within eight months of its filing date or date of commencement of national stage in an international application." The rule also "contains miscellaneous changes pertaining to the supplemental examination, inventor's oath or declaration, and first inventor to file provisions of the Leahy-Smith America Invents Act."

Parliament Approves New Safety Regulations for Medical Devices in Europe

The European Parliament reportedly passed legislation on October 22, 2013, that will strengthen the safety-testing body oversight of medical devices and require such products to be more easily traced once on the market. The decision was made during a plenary session, and members will begin negotiations with European Union (EU) members to finalize the rules.

"We talk about products which are supposed to help patients in their suffering, in their illness," EU member Dagmar Roth-Behrendt of Germany said. "We should assist doctors in making sure they are using the best possible products when they want to assist their patients."

According to a news source, the EU announced plans in September 2012 to strengthen medical device regulation in the wake of a scandal over the safety of alleged fraudulent silicone breast implants manufactured by a now-defunct French company. Under the new legislation, patients who receive an implant would apparently register for the device and receive an "implant card," designed to alert them to incidents involving similar devices. Lawmakers have also requested that physicians and patients be given sufficient access to clinical data about the products.

The legislation would further require (i) the bodies that oversee medical device safety to employ an in-house team of experts to review the products, rather than rely on subcontractors; and (ii) the establishment of a special group to review devices considered to carry the highest risks, such as those implanted inside the body. *See Law 360* and *European Parliament Press Release,* October 22, 2013.

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LITIGATION

Myriad Genetics Files More BRCA1 and BRCA2 Patent-Infringement Suits

Myriad Genetics has filed patent-infringement actions in a Utah federal court against BioReference Laboratories' GeneDx and Quest Diagnostics, claiming that the companies have infringed patents covering the BRCA1 and BRCA2 genes. *Univ. of Utah Research Found. v. GeneDX, Inc.*, No. 13-0954 (U.S. Dist. Ct., D. Utah, Cent. Div., filed October 16, 2013); *Univ. of Utah Research Found. v. Quest Diagnostics, Inc.*, No. 13-0967 (U.S. Dist. Ct., D. Utah, Cent. Div., filed October 22, 2013). The plaintiffs include co-owners of the patents, which were upheld by the U.S. Supreme Court to the extent they involve synthetic DNA. The patented genes are used in molecular diagnostic testing for cancer.

Quest Diagnostics brought a complaint against Myriad Genetics in a California federal court about two weeks before Myriad named it as a defendant in Utah; Quest sought a declaration of non-infringement and the invalidity of Myriad's patents. *Quest Diagnostics, Inc. v. Myriad Genetics, Inc.*, No. 13-1587 (U.S. Dist. Ct., C.D. Cal., filed October 10, 2013). Myriad is aggressively defending its patent portfolio and contends that it still has 500 valid and enforceable claims in the 24 patents underlying its diagnostic test. According to the company, "The BRCA patent owners continue to believe that patent claims related to BRCA1 and BRCA2 gene testing are valid and enforceable and will demonstrate that the testing process used by [defendants] infringes those claims." *See GenomeWeb*, October 22, 2013.

NEWS BYTES

The U.S. Food and Drug Administration (FDA) **issues** a report titled "Paving the Way for Personalized Medicine: FDA's Role in a New Era of Medical Product Development" to describe how it has "evolved its regulatory processes in response to—and anticipation of—scientific developments that are critical for the development of personalized therapeutics and diagnostics." The agency defines "personalized medicine" as "the tailoring of medical treatment to the individual characteristics, needs, and preferences of a patient during all stages of care, including prevention, diagnosis, treatment, and follow-up.

The U.S. Food and Drug Administration (FDA) **schedules** a public meeting to obtain input on scientific approaches for conducting and assessing meta-analyses of randomized controlled trials to evaluate safety risks of human drugs or biological products. Information from the meeting will be used to develop draft guidance that describes best practices and FDA's intended approach for the use of meta-analyses in regulatory decision making. Specifically, the guidance will describe the criteria FDA deems

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important when evaluating the strength and quality of evidence provided by a meta-analysis. Participants should register by November 18. The workshop will also be available via streaming Webcast.

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Pharmaceutical and Medical Device Litigation Partner **Debra Dunne** will join a distinguished faculty November 6-7, 2013, in New Brunswick, New Jersey, during the Food and Drug Law Institute's (FDLI's) "Introduction to Drug Law & Regulation: The Legal Framework for Drug Regulation." Dunne will present on "Over-the-Counter (OTC) Drugs." This introductory **program** provides a systematic and comprehensive overview of the laws and regulations within the Food and Drug Administration's bailiwick.

The Product Quality Research Institute, U.S. Pharmacopeial (USP) Convention and American Association of Pharmaceutical Scientists have **scheduled** a nanotechnology workshop for January 14-15, 2014, at the USP Meeting Center in Rockville, Maryland. Titled "Nanomaterial Drug Products: Current Experience and Management of Potential Risks," the workshop will feature presentations by industry representatives, academics and government regulators.

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