ISSUE 61 | AUGUST 1, 2013

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Advisory Council Issues Model Order on Excess Claims and Prior Art

The Federal Circuit Advisory Council on July 22, 2013, issued a **model order** to address excessive patent claims and prior art references in patent cases.

While not currently available on the Federal Circuit's Website and lacking binding authority, the order provides guidance to trial courts by establishing default numerical limits for patent litigants on the number of preliminary elections of asserted patent claims and prior art references—10 claims from each patent and not more than 32 claims; 12 prior art references and not more than 40 references. It would also limit final elections to five asserted claims per patent from among the 10 previously identified claims, with no more than 16 claims total, and six asserted prior art references per patent from among the 12 previously identified art references, with no more than a total of 20 references. The limits can be modified "for good cause shown" by the parties.

JOINT VENTURES

Diagnostics Companies Join to Provide Infectious-Disease Testing in Developing Countries

According to a news source, Co-Diagnostics has entered a joint venture with DNA Logix to bring genetic-testing products and services to high-burden developing countries (HBDCs) as part of an effort to address the diagnostic problems associated with infectious diseases unique to those countries. The joint venture, named Co-Diagnostics HBDC, will be based on polymerase chain reaction testing developed by DNA Logix and licensed to the joint venture specifically for sale in HBDCs. DNA Logix CEO Brent Satterfield said about the agreement, "There is a lot of unmet need in the world, and we believe that innovative testing technologies, combined with forward-thinking business models will allow us to reach a much larger number of people." Both companies are based in Utah. *See Genetic Engineering & Biotechnology News* and *GenomeWeb*, July 24, 2013.

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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INVESTOR NEWS

Cancer Biotech Raises $106 Million in IPO

Cambridge, Massachusetts-based Agios Pharmaceuticals, Inc. has reportedly closed its initial public offering (IPO) of more than 6.7 million shares of common stock, raising $106 million at an IPO price of $18 per share. The company also intends to offer an additional 883,000 shares for overallotments, according to a news source. The company has several drug candidates that target cellular metabolism to treat cancer and rare genetic disorders known as inborn errors of metabolism or IEMs. According to a company statement, "We intend to apply our deep understanding of metabolism, coupled with our ability to create medicines that can inhibit or activate metabolic enzymes, to fundamentally change the way cancer and IEMs are treated." *See Agios Pharmaceuticals News Release*, July 29, 2013.

Fetal DNA Diagnostics Startup Seeks $10 Million

KellBenx Inc., a New York-based startup focused on developing a non-invasive DNA test that will analyze fetal cells that are intact within maternal blood samples as an alternative to traditional prenatal blood tests, has filed a statement with the Securities and Exchange Commission indicating its intent to raise $10 million in a securities offering. Founded in 2010 by CEO Hassan Bannani and President and Chair Leonard Kellner who both previously worked at a women's health-focused lab, the company is also working on a breakthrough test to determine whether a woman is likely to deliver prematurely. *See MDDIonline.com*, July 22, 2013.

Biopharmaceutical Company Completes Public Offering to Fund MicroRNA Therapeutics

Regulus Therapeutics Inc. has reportedly completed an underwritten public offering of 5.175 million shares of common stock, including 675,000 shares sold under the full exercise of an underwriters' option to purchase additional shares. Gross proceeds from the offering were approximately $49.2 million. The LaJolla, California-based biopharmaceutical company develops medicines targeting microRNAs, among them RG-101 for the treatment of the Hepatitis C virus. It is also advancing its other microRNA therapeutics into clinical development in areas including oncology, fibrosis and metabolic diseases. *See Regulus Therapeutics Inc. Press Release*, July 23, 2013.

Developer of Autism Spectrum Disorder Diagnostics Raises $15.4 Million

SynapDx Corp. has reportedly secured $15.4 million in a funding round led by Google Ventures and joined by new investor Foundation Medical

Partners and founding investors North Bridge Venture Partners and General Catalyst Partners. The funding will support the Massachusetts-based startup's work on a blood-based autism spectrum disorder (ASD) diagnostic test that will allow clinicians to identify children with autism earlier than possible with existing diagnostics.

The company is apparently studying the genetic makeup of children clinically diagnosed with ASD to better understand how to design a more accurate blood test that will signal for the disorder. Google's Andrew Conrad, newly appointed to SynapDx's board, said, "The best diagnostic tests of our era will be developed at the nexus of advanced genomics and cutting edge informatics." *See SynapDx Corp. News Release* and *TechCrunch.com*, July 22, 2013.

Diabetes and Obesity Biotech Secures $50 Million in Series C Financing Round

According to a news source, NGM Biopharmaceuticals, Inc. has completed a $50-million Series C financing round that included new investors from the Topspin Fund and existing investors including The Column Group, Prospect Venture Partners, Rho Ventures, and Tichenor Ventures. NGM CEO William Rieflin said, "We remain focused on delivering the next generation of first-in-class therapeutics for the treatment of diabetes and other cardio-metabolic diseases." Headquartered in South San Francisco, NGM has reportedly raised more than $130 million since it was founded in 2008 and has spent much of its resources and time doing basic research to uncover how hormones and receptors regulate diseases such as diabetes, obesity, muscle wasting, and cardiovascular disorders. *See NGM Biopharmaceuticals, Inc. Press Release*, July 18, 2013; *San Francisco Business Times*, July 19, 2013.

Biotech Raises $30 Million to Develop Rare Muscle Disease Treatments

San Francisco-based Audentes Therapeutics Inc. has closed a $30-million Series A financing round led by OrbiMed Advisors and including 5AM Ventures and Versant Ventures. The proceeds will reportedly be used to advance the company's two lead programs, AT001 for X-linked myotubular myopathy, an inherited disorder characterized by severe muscle weakness and respiratory impairment affecting some 1 in 50,000 newborn males worldwide, and AT002 for Pompe disease, a rare, inherited disorder caused by gene mutations and manifesting in progressive muscle weakness and respiratory impairment affecting 1 in every 40,000 births. These treatments are apparently based on adeno-associated virus gene therapy technology. According to Audentes President and CEO Matthew Peterson, "This financing is a tremendous step forward for the development of new potential treatments for patients affected by very serious orphan muscle diseases." *See Audentes Therapeutics Inc. Press Release*, July 18, 2013.

BUSINESS CLIMATE

Biotech IPO Boom Continues

According to *Xconomy's* National Biotech Editor Luke Timmerman, the 24 biotech initial public offerings (IPOs) in 2013 are double those normally seen in an entire year since the financial crisis made investors more cautious about biotech investments. He reports that five more IPOs were expected as July came to a close. Timmerman, however, does not believe that "this IPO party" will last much longer. He cautions, "There are only so many good private companies worthy of graduating to the public markets. If the past is any indication (remember the genomics craze of 2000?), there will be a hangover when it ends." *See Xconomy.com*, July 22, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

CRS Report Focuses on Pharmaceutical Patent Settlements

The Congressional Research Service (CRS) recently issued a report titled "Pharmaceutical Patent Settlements: Issues in Innovation and Competitiveness" that addresses options Congress may consider following the U.S. Supreme Court's June 2013 ruling that the reverse-payment settlement of a pharmaceutical infringement action could violate U.S. antitrust law even if the agreement's "anticompetitive effect falls within the scope of the exclusionary potential of the patent." Additional information about the ruling appears in Issue **59** of this *Bulletin*.

The Court held that these settlements must be evaluated under the "rule of reason" approach, leaving the lower courts, according to CRS, to face "the potentially complex task of applying the rule of reason to reverse payment settlements going forward." Reverse, or "pay-for-delay," settlements resolve patent infringement actions brought by brand-name pharmaceutical companies against their generic competitors. Often, they call on the generic firm to refrain from challenging the brand-name patent and from selling the generic version of the patented drug for a period of time in exchange for payments from the patent owner.

The report notes that Congress could await further judicial developments or regulate reverse-payment settlements "in some manner." Several bills pending before the 113th Congress approach the issue by either establishing a presumption of legality or illegality under the antitrust laws or revising food and drug laws to reduce the incentives for generic firms to settle with brand-name manufacturers. Acknowledging the significance

of the issue to the U.S. public health system, CRS opines, "When concluded in a manner that comports with antitrust principles, such settlements may further the public policy goals of encouraging the labors that lead to medical innovation, but also distributing the fruits of those labors to consumers."

Meanwhile, the U.S. Senate recently held a hearing on a proposal sponsored by Sens. Amy Klobuchar (D-Minn.) and Charles Grassley (R-Iowa) that would make "pay-for-delay" deals illegal unless the parties can prove that they are not anticompetitive. Klobuchar claims that the agreements lead to consumers paying higher prices for drugs, and the Congressional Budget Office has reportedly estimated that the pending legislation would save the government some $4.7 billion over 10 years by allowing lower-priced generic drugs to enter the marketplace more quickly. Opponents contend that the agreements do not extend the amount of time a patent provides exclusivity. Sen. Mike Lee (R-Utah) reportedly commented that "[m]ost of the time they end up shortening the term of the patents by allowing generic manufacturers to enter the market before the patent has expired."

According to Federal Trade Commission (FTC) Chair Edith Ramirez, who testified during the hearing, the commission is planning aggressive attacks on "pay-for-delay" settlements in response to the U.S. Supreme Court's ruling, which, in the agency's view, strengthened the agency's hand. She reportedly urged the Senate to pass the proposed bill and place the burden on drug companies to prove that the agreements are not anticompetitive. Ramirez said, "While the rule of reason standard is an appropriate test and we intend to apply that going forward, I do believe declaring them presumptively invalid would also further help us put a stop to these types of settlements." The U.S. Supreme Court rejected FTC's *per se* invalid approach. *See Businessweek.com* and *BLT: The Blog of Legal Times*, July 23, 2013.

Compounding Bill Amendments Could Delay Passage

A bipartisan coalition of senators from the U.S. Senate Committee on Health, Education, Labor, and Pensions has reportedly urged action on a bill (S. 959) that would give the Food and Drug Administration (FDA) additional authority over compounded drugs, which have traditionally been subject to state oversight. They released an updated **version** of the proposal on July 25, 2013, to clarify which compounders and drugs would be within FDA's bailiwick and address the concerns of opponents who have questioned the original bill's approach since it was placed on the Senate calendar in June. At least one Senate Republican has reportedly indicated that more time and review will be required before it can

be approved and suggested that it will not be passed before the August recess. *See CQ News*, July 25, 2013; *U.S. Senate Committee on Health, Education, Labor, & Pensions News Release*, July 25, 2013.

In a related development, a Massachusetts bankruptcy court has entered an order declaring that the New England Compounding Center, linked to a deadly nationwide meningitis outbreak that is the driving force behind the congressional bill, was insolvent when it filed for Chapter 11 bankruptcy. *In re New England Compounding Pharmacy, Inc.*, No. 12-19882 (Bankr. D. Mass., E. Div., order entered July 24, 2013). The ruling will clear the way for victims to pursue claims against health care providers and other entities that distributed the products in a currently pending multi-district litigation (MDL) or in proceedings subject to removal or transfer to the MDL proceeding.

LITIGATION

Federal Court Rejects Punitive Damages in Bone Drug Litigation

A federal court in Florida has granted a drug maker's request to apply New Jersey law to the plaintiffs' punitive damages demand in litigation alleging that the use of medicines approved by the U.S. Food and Drug Administration (FDA) to treat bone metastasis caused the jaw osteonecrosis developed by the plaintiff wife. *Dopson-Troutt v. Novartis Pharms. Corp.*, No. 06-1708 (U.S. Dist. Ct., M.D. Fla., Tampa Div., order entered July 22, 2013).

The court agreed with the defendant that while Pennsylvania law may apply to certain issues in the case because that is where the plaintiffs reside and the injury occurred, (i) the court should conduct a separate choice-of-law analysis for punitive damages, (ii) Florida choice-of-law principles would require the application of New Jersey law to punitive damages, and (iii) the plaintiffs may not seek punitive damages under New Jersey law.

The court applied a choice-of-law doctrine known as dépeçage, a principle that requires conflicts to be evaluated with respect to a particular issue in a case, and not to the case as a whole, finding that Florida, the forum state, recognizes the doctrine. In ruling that New Jersey law applied to the punitive damages issue, the court reasoned that the alleged misconduct to be punished by a punitive damage award involved the New Jersey-based company's decisions as to labeling, packaging and warnings, all of which occurred in New Jersey, giving the state a more significant relationship to the matter.

New Jersey law provides immunity to drug companies from punitive damages in product liability cases where FDA has approved the drug, although an exception allows recovery if the plaintiff can show that the drug company "knowingly withheld or misrepresented information required to be submitted under [FDA] regulations." The court determined that the exception was preempted under federal law because it would conflict with the agency's "responsibility to police fraud consistently with the Administration's judgment and objectives."

FDA Prosecutes Drug Importer on Counterfeit Drug Charges

The U.S. Food and Drug Administration (FDA) recently announced that a Montana resident who served as a consultant to a company that imported counterfeit cancer drugs was sentenced following his guilty plea to misprision of a felony. According to a Department of Justice press release, a federal court has sentenced Paul Bottomley to five years of probation with six months of home confinement, civil forfeiture of $4.4 million and 200 hours of community service.

The FDA apparently alleged that Bottomley owned Montana Health Care Solutions (MHCS), which opened in 2008 and was sold in 2010 to Rockley Ventures, Ltd. MHCS allegedly distributed drugs from foreign countries to American physicians with labels that did not conform to FDA-approved labeling for U.S. versions of the drugs. After MHCS was sold, Bottomely remained as a paid advisor and made sales calls to physicians on behalf of the company which allegedly imported and sold counterfeit oncology drugs that did not contain the active drug ingredients in legitimate versions. The charge to which Bottomley entered a plea would have required FDA to prove that he knew about the alleged felony, failed to notify authorities and concealed the crime.

According to an FDA blog post about the sentencing, Bottomley "acted out of greed," selling potentially dangerous unapproved and misbranded pharmaceuticals at discounted prices to American physicians solely for profit. *See U.S. Department of Justice Press Release*, July 12, 2013; *FDA Voice*, July 15, 2013.

NEWS BYTES

The U.S. Food and Drug Administration (FDA) **issues** final guidance for industry titled "Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD&C Act." The document provides information describing (i) the types of safety labeling changes that certain drug and biological product application holders might be required to make under the Food

and Drug Administration Amendments Act of 2007 in light of safety information that becomes available after the drug or biological product has been approved; (ii) "how FDA plans to determine what constitutes new safety information; [iii] the procedures involved in requiring safety labeling changes; and [iv] enforcement of the requirements for safety labeling changes." Comments may be submitted at any time.

The U.S. Patent and Trademark Office **extends** until August 21, 2013, the deadline for public comment "regarding the processes, data metrics, and methodologies that could be used to assess the effectiveness of cooperative agreements and other voluntary initiatives to reduce intellectual property infringement that occurs online—such as copyright piracy and trademark infringement" as part of its "Voluntary Best Practices Study."

The U.S. Food and Drug Administration (FDA) **issues** a notice as to the availability of a draft guidance for industry titled "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection." The guidance defines "the types of action, inaction, and circumstances that FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection," when FDA has concerns about adulterated drugs. Comments on the draft are requested by September 13, 2013.

The U.S. Food and Drug Administration **announces** the availability of draft guidance for industry titled "Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans" (PSPs). The document is intended "to assist sponsors in the submission of an initial PSP and any amendments to the PSP," including who must submit these plans, when they must be submitted and what should be included in the plans. Comments on the draft are requested by September 13, 2013.

The Centers for Disease Control and Prevention (CDC) **issues** a direct final rule and request for comments on certain housekeeping changes to regulations titled "Distribution of Reference Biological Standards and Biological Preparations," at 42 C.F.R. Part 7. The changes include updating references to the CDC, which has undergone a name change since the regulations were adopted, and a mailing address. Unless significant adverse comment is submitted before August 21, 2013, the rule will take effect September 20.

The U.S. Food and Drug Administration **schedules** a public workshop "to bring together a broad range of stakeholders to discuss current and future standards development activities involving cellular therapies and regenerative medicine products." Those wishing to participate should register by September 23, 2013. The October 7 workshop will also be available via

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streaming Webcast. The agency is hoping to coordinate existing efforts in this arena and will also discuss "areas of high interest for current or future standards development" and "explore ways to minimize redundancy and maximize collaboration."

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