Shook, Hardy & Bacon L.L.P.

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# LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS



## IP NEWS

### Tech Entrepreneur Advocate Calls Out Congress for Failure to Enact Patent Reform

In an open letter to the press, policymakers and the technology community, the executive director of Engine, an advocacy organization for technology entrepreneurship, has called the Senate's failure to vote on patent-reform legislation that would have curbed the excesses of non-practicing entities (NPEs)—those organizations that focus their efforts on making money by litigating patent-infringement claims—an unpleasant surprise, but not a loss. According to Julie Samuels, the media got the story wrong by calling tech "D.C.'s biggest loser," noting that "this Congress is notorious for getting nothing done. It should come as no surprise that tech's causes are not miraculously turning into legislation. No one's are."

Samuels also claimed that Washington, D.C.'s policy makers have failed to recognize that the "tech community" is "actually becoming the American electorate at large. Soon, there will be no distinction between the tech community and the rest of the country. As today's digital natives turn 18, they all become tech voters." She reminded the tech community that it is already having an impact on NPEs, contending that they "are on the defensive" with courts shifting fees to the losers of "spurious lawsuits" and taking a closer look at NPE practices and patent quality. She also reminded them that the U.S. Federal Trade Commission is investigating NPEs and protecting consumers from their worst behaviors. She concludes, "Our efforts have changed substantive debates in many areas, and have significantly moved the state of the law—even without passing legislation yet this year." *See Recode.net*, June 5, 2014.

### Drug Patent-Protection Incentives Needed?

Noting that several members of Congress recently demanded that a pharmaceutical company justify the high cost of its hepatitis C drug, the editor-in-chief of *Life Science Leader* magazine suggests that patent protections for prescription medications may need to be changed and

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additional incentives offered to achieve the goal of inexpensive drugs. Rob Wright praises the Orphan Drug Act for providing certain incentives, such as waiving some fees and providing tax credits, as well as prescribing "a seven-year period of market exclusivity after [Food and Drug Administration] approval" to address the slow development of rare disease drugs. But he notes that none of the incentives requires that the products be "cheap." Wright calls for the consideration of longer patents or tying longer patents "to how quickly a company is able to execute its R&D plan or [tying] it to a step-down, drug-pricing exchange model." In his view, "[a]llowing the application of a 'one-size-fits-all' intellectual property policy that affords the same protection for Frisbees as lifesaving and sustaining medicines would be, quite frankly, moronic and short-sighted." *See Life Science Leader*, May 30, 2014.

## INVESTOR NEWS

### Philadelphia Gene-Therapy Company Raises $72.8 Million

Children's Hospital of Philadelphia (CHOP) gene-therapy spinoff Spark Therapeutics, Inc. has reportedly raised $72.8 million in a Series B funding round led by Silicon Valley-based Sofinnova Ventures. CHOP also participated in the round along with Brookside Capital, Deerfield Management Co., Rock Springs Capital, T. Rowe Price Associates, Inc., Wellington Management Co., LLP, and two undisclosed healthcare funds.

According to Spark co-founder and CEO Jeffrey Marrazzo, proceeds from the round will be used to expand the company's pipeline of gene-therapy programs, including development of its lead Phase 3 program to treat RPE65-related blindness, as well as support company growth during the next three years. He said, "The funding will support the expansion of our team and ongoing development of our pipeline as we build the infrastructure needed for a first-in-class, FDA-approved gene therapy." *See Spark Therapeutics Inc. News Release*, May 27, 2014.

### Biotech with Eye Disease Focus Files for $74.8-Million IPO

San Diego, California-based Pfenex Inc., which develops retinal disease treatments, has **filed** a registration statement with the U.S. Securities and Exchange Commission indicating its intent to raise up to $74.8 million in an initial public offering (IPO).

Pfenex develops biosimilars—generic version of biologic drugs—including its flagship product, PF582, a biosimilar of a monoclonal antibody drug used to treat wet age-related macular degeneration (AMD), an eye disease that causes vision loss. The company is currently

conducting Phase 1b/2a trials of PF582 in AMD patients and reportedly expects to enter Phase 3 trials in mid-2015. *See Pfenex News Release*, June 6, 2014.

**Quantapore Secures $35 Million for DNA Sequencing**

Biotech Quantapore Inc. has reportedly received $35 million in new venture capital funding that the company apparently plans to use to finalize development of its proprietary DNA sequencing technology as well as commercialize its sequencing platform. From its Menlo Park, California, headquarters, Quantapore is developing a new nanopore-based nucleic acid sequencing technology that evidently allows for longer "reads"—DNA sequences that help researchers see how genetic material is organized—that could provide better views of DNA and give doctors more accurate information for treating patients. *See SanFranciscoBusiness Times.com*, May 21, 2014.

**NIH Awards $600,000 to Johns Hopkins Incubator Start-Up**

The U.S. National Institutes of Health (NIH) has awarded Twistnostics, LLC a number of grants since it was founded in 2011 by Johns Hopkins alumni, including, most recently, $600,000 to develop an automated gram-negative bacteria microarray test. Located at the FastForward incubator of Johns Hopkins University in Baltimore, Maryland, the biotechnology and medical device start-up developed the Twist-Biosensor, proprietary technology for "rapid and ultra-sensitive detection of biomolecules," and is focusing on using it to develop diagnostics assays for early cancer detection, personalized medicine and rapid detection of infectious diseases. The company has also received funding from the National Human Genome Research Initiative and National Cancer Institute. *See NIH Funding Report*, June 2, 2014; *Genomeweb.com*, June 3, 2014.

**Heart Transplant Monitor Company Files for $50-Million IPO**

CareDx Inc. has **filed** a registration statement with the U.S. Securities and Exchange Commission indicating its intent to raise up to $50 million in an initial public offering (IPO).

The Brisbane, California-based company, which sells molecular diagnostic tests to monitor heart transplants, had previously filed and then shelved an $86-million IPO in 2007 under the name XDx, according to a news source. Piper Jaffray, Leerink Partners, Raymond James, and Mizuho Securities are joint bookrunners on the deal. Pricing terms have not been disclosed. *See SiliconValleyBusinessJournal.com*, June 4, 2014.

## BUSINESS CLIMATE

### Duke U. Economics Prof Discusses Prospects for Biosimilars in U.S.

Duke University Professor Emeritus and Director of the Program in Pharmaceutical Health Economics Henry Grabowski has co-authored a paper on biosimilar development for the June 2014 issue of *Health Affairs*. Titled "Regulatory and Cost Barriers Are Likely to Limit Biosimilar Development and Expected Savings in the Near Future," the paper cites high development costs, interchangeability requirements and competition from new biologics in the same therapeutic class as impediments to a dynamic biosimilars market in the United States, at least in the short term. Grabowski claims that such expectations are generally consistent with the development of biologics in Europe since 2007. While policymakers had hoped that biosimilars could deliver the same types of cost savings as generics, Grabowski contends that they may not achieve such savings for 10 years or more, but will do so once equivalence can be shown without costly clinical studies and prescribers become more receptive to their use. *See The Hill*, June 3, 2014.

## LEGISLATIVE AND REGULATORY DEVELOPMENTS

### FDA Launches OpenFDA Database with Reports on Prescription Drug Side Effects

The U.S. Food and Drug Administration (FDA) has **launched** a database that pulls together large amounts of data to enable "those in private and public sectors [to] use FDA public data to spur innovation, advance academic research, educate the public, and protect public health." The "openFDA" launch is a pilot that involves millions of reports of drug adverse events and medication errors submitted to the agency between 2004 and 2013.

In the past, this data was apparently available only through Freedom of Information Act requests. Software developers will now be able to build mobile phone applications or interactive Websites that can search, query or gather large amounts of public information "instantaneously and directly in real time on an 'as-needed' basis." According to FDA, this would enable consumers with such apps on their smart phones "to determine whether anyone else has experienced the same adverse event they did after taking a certain drug." In the future, FDA will expand the database to include product recall and labeling data. *See FDA News Release* and *FDAVoice Blog*, June 2, 2014.

**USPTO and KIPO Expand Collaboration on Patent Classification Activities**

With an aim to "streamline" the application process and "improve" examination quality, the U.S. Patent and Trademark Office (USPTO) and the Korean Intellectual Property Office (KIPO) have announced their expanded cooperation in patent classification activities. To that end, KIPO will reportedly increase the number of technical areas in which it classifies patent documents using the Cooperative Patent Classification (CPC) system—a USPTO and European Patent Office jointly managed classification system, which debuted January 1, 2013.

"KIPO plans to gradually expand the technical fields in which the CPC is used in KIPO and will continue to work with the USPTO in this effort," said KIPO Commissioner Young-min Kim. "It is expected that the use of the unified classification system . . . will contribute to highly efficient retrieval of patent documents in the expanded technical fields." *See USPTO News Release*, June 5, 2014.

**NIH Backs New Genetic Research Center**

The U.S. National Institutes of Health (NIH) has awarded $25 million to the not-for-profit J. Craig Venter Institute (JCVI) to establish and operate a Genome Center for Infectious Diseases. Scientists at JCVI, which has offices in Maryland and California, will use the five-year grant to study the genetic characteristics of various bacteria, viruses and parasites, as part of an effort to develop treatments and preventative measures for infectious diseases such as malaria and influenza. JCVI investigators will lead the research along with more than 50 collaborators at approximately 40 international research organizations.

"This grant is going to allow us to get a better understanding of emerging infectious diseases and microbial resistance," said JCVI President Karen Nelson. "It's also going to push the envelope in having the biggest database, for example, in the viral world. We have sequenced the most influenza genomes to date, and we're going to expand that."

Among other things, program goals include (i) enhancing understanding of pathogen drug resistance and identifying approaches to manage human infections by drug-resistant organisms; (ii) gaining new insight into microbial diversity and the evolution of pathogen populations and how they affect human infectious diseases; (iii) identifying mechanisms and consequences of pathogen modulation of host response to infection and understanding how the pathogen interacts with host immune systems and microbiomes; (iv) characterizing the genomic variation in and virulence of infectious diseases; and (v) exploring human immunity to malaria and influenza.

Research findings and outcomes will reportedly be available to the broad scientific community without proprietary restrictions. *See JCVI News Release* and *UTSanDiego.com*, June 5, 2014.

### EU Agency Will Reinstate Ranbaxy's GMP Certificate

The European Medicines Agency (EMA) has reportedly concluded its investigation of alleged non-compliance with good manufacturing practice (GMP) at Ranbaxy Laboratories' facility in Toansa, India, and will reinstate the GMP certificate that was suspended in January 2014. While EMA's assessment apparently revealed a number of GMP deficiencies, EU regulators have concluded that they did not place public health at risk. The EU inspection followed non-compliance findings by the U.S. Food and Drug Administration (FDA), which prohibited imports from the facility beginning in January 2014. Additional details about FDA's action appear in Issue 71 of this *Bulletin*.

According to EMA, the European inspection showed that "appropriate corrective and preventive measures have been put in place by the manufacturer, [and] there was no evidence that any medicines on the EU market that have an active pharmaceutical ingredient manufactured in Toansa were of unacceptable quality or presented a risk to the health of patients taking them." *See EMA News Release*, June 5, 2014.

## LITIGATION

### SCOTUS Reverses Federal Circuit Patent Ruling

The U.S. Supreme Court has reversed a Federal Circuit Court of Appeals decision on induced infringement, ruling that a defendant cannot be held liable for inducing infringement under 35 U.S.C. § 271(b) when no one has directly infringed the patent under § 271(a) or any other patent law. ***Limelight Networks, Inc. v. Akamai Techs., Inc.*, No. 12-786 (U.S. June 2, 2014)**. Additional details about the lower court's ruling appear in Issue 42 of this *Bulletin*.

Here, the party alleged to have induced infringement carried out several steps of the method patent and provided instructions and technical assistance for its customers to take the remaining steps. The Federal Circuit determined that a defendant could be liable for inducing infringement even if no one has committed direct infringement under the patent laws, "because direct infringement can exist independently of a violation of these statutory provisions." The court relied on *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008), which would have held a

defendant liable for infringement under § 271(a), if it exercised sufficient control or direction over its customers' performance of the patent steps that the defendant did not perform.

Writing for the unanimous Court, Justice Samuel Alito noted that the alleged infringement involved a method patent and, unless a single entity completes every step of the patent, it has not been directly infringed. So ruling, the Court observed, "The Federal Circuit's analysis fundamentally misunderstands what it means to infringe a method patent. A method patent claims a number of steps; under the Court's case law, the patent is not infringed unless all the steps are carried out." The Court declined an invitation to overrule the *Muniauction* rule, because the certiorari grant did not involve § 271(a). On remand, however, "the Federal Circuit will have the opportunity to revisit the § 271(a) question if it so chooses."

**Court Finds No Standing for Consumer Watchdog in Stem Cell Patent Appeal**

The Federal Circuit Court of Appeals has rejected not-for-profit Consumer Watchdog's appeal of the U.S. Patent and Trademark Office's (USPTO's) determination that Wisconsin Alumni Research Foundation (WARF) could retain patent rights to human embryonic stem cell cultures. *Consumer Watchdog v. Wis. Alumni Research Found.*, No. 13-1377 (Fed. Cir., order entered June 4, 2014). Consumer Watchdog challenged WARF's stem cell patent under the inter partes system, which allows a member of the public to file for patent reexamination, claiming that the patent hindered scientific research. After USPTO affirmed its decision to issue WARF's patent, Consumer Watchdog appealed to the Federal Circuit Court of Appeals, which dismissed the appeal because of Consumer Watchdog's failure to establish an injury in fact sufficient to confer standing to the organization.

To invoke federal jurisdiction by proving standing, the court explained, the party must show that (i) "it has suffered an 'injury in fact' that is both concrete and particularized, and actual or imminent (as opposed to conjectural or hypothetical)"; (ii) "the injury is fairly traceable to the challenged action"; and (iii) "it is likely, rather than merely speculative, that a favorable judicial decision will redress the injury." The court further noted that the latter two requirements may be relaxed under the direction of Congress—such as when Congress has given parties the right to appeal the decision of an administrative agency like USPTO—but that even then the party must allege an injury in fact rather than a mere general grievance.

Consumer Watchdog failed to show standing, the court held, because the organization did not prove any injury in fact. "Consumer Watchdog does not allege that it is engaged in any activity involving human embryonic

stem cells that could form the basis for an infringement claim. It does not allege that it intends to engage in such activity. Nor does it allege that it is an actual or prospective licensee, or that it has any other connection to the [WARF stem cell] patent or the claimed subject matter." Instead, Consumer Watchdog's appeal amounted to a general grievance only.

**Federal Court Upholds FTC Rules on Reporting Certain Pharma Patent Transfers**

Granting the agency's motion for summary judgment, a federal court in the District of Columbia has upheld the U.S. Federal Trade Commission's (FTC's) authority to adopt an industry-specific rule under the Hart-Scott-Rodino [HSR] Antitrust Improvements Act and thus left in place a rule that would require pharmaceutical companies to report certain grants of an exclusive right to commercially use a patent or part of a patent as a "potentially reportable asset acquisition under the [HSR] Act." *Pharm. Research & Mfrs. of Am. v. FTC*, No. 13-1974 (U.S. Dist. Ct., D.D.C., decided May 30, 2014).

So ruling, the court rejected the challenger's arguments that FTC could not issue an industry-specific rule under the law and that the agency failed to establish a rational basis for the rule and to comply with legally required procedures. Additional details about the proposal, which was adopted without change, appear in Issue **40** of this *Bulletin*. Regulated under the rule are two categories of patent rights transfers, "where the licensor retains only manufacturing rights or co-rights." FTC found that such transfers "'carr[y] the same potential anticompetitive effects' as buying a patent outright," and that they are particularly prevalent in this industry.

## NEWS BYTES

The U.S. Food and Drug Administration (FDA) **issues** a final rule amending its "postmarketing safety reporting regulations for human drug and biological products to require that persons subject to mandatory reporting requirements submit safety reports in an electronic format that FDA can process, review, and archive." Effective June 10, 2014, the rule is intended to help the agency "more rapidly review postmarketing safety reports, identify emerging safety problems, and disseminate safety information." FDA has also **issued** draft guidance titled "Providing Submissions in Electronic Format—Postmarketing Safety Reports," to help those subject to the new rule comply with its requirements. Comments on the draft guidance are requested by August 11, 2014.

The U.S. Food and Drug Administration (FDA) **issues** a final rule listing those pathogens with the potential to pose a serious threat to public health, thus fulfilling a requirement of the Food and Drug Administration

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Safety and Innovation Act to "encourage development of new antibacterial and antifungal drugs for the treatment of serious or life-threatening infections." As part of the mandate, FDA was required to consider including those "qualifying pathogens" posing a particular threat of drug resistance to humans.

The U.S. Food and Drug Administration (FDA) **makes** available draft industry guidance titled "Best Practices in Developing Proprietary Names for Drugs." Among other matters, the draft "focuses on the safety aspects in the development and selection of proposed proprietary names for all prescription and nonprescription human drug products and biological products[,] . . . describes naming design practices to help avoid medication errors and provides a qualitative systematic framework for evaluating proprietary names before submitting them for FDA review." Written comments are requested by July 28, 2014.

The U.S. Food and Drug Administration (FDA) **issues** a final rule that implements its authority to detain drugs intended for human or animal use when "an authorized FDA representative conducting an inspection has reason to believe [they] are adulterated or misbranded." Intended to "protect the public by preventing distribution or subsequent use of drugs encountered during inspections that are believed to be adulterated or misbranded, until FDA has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate," the rule takes effect June 30, 2014.

The U.S. Patent and Trademark Office (USPTO) **announces** the June 30, 2014, opening of its permanent satellite office in Denver, Colorado.

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