Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

USPTO Director Clarifies Jurisdiction of New Patent Trial and Appeal Board

In response to online debate over whether the new Patent Trial and Appeal Board may consider patentability challenges under 35 U.S.C. § 101 in post-grant review or covered business method review proceedings, U.S. Patent and Trademark Office (USPTO) Director David Kappos recently explained the office's interpretation of the relevant America Invents Act provisions. According to Kappos, because § 101 is a "condition for patentability" under U.S. Supreme Court and Federal Circuit precedent, the board may consider patentability challenges in post-grant reviews and covered business method reviews. He notes that the legislative history supports this view. *See Director's Forum: David Kappos' Public Blog*, September 24, 2012.

Federal Circuit Dubbed a "Rogue Appeals Court," Seen as Biased in Favor of Patent Holders

Writing for *Ars* Technica in an article titled "How a rogue appeals court wrecked the patent system," associate writer Timothy Lee explores the history of the Federal Circuit Court of Appeals, noting that it was created in 1982 due to "concerns about the lack of uniformity in patent law [that] had become widespread." With sole appellate jurisdiction over patent disputes, the court accomplished congressional goals by making patent law more uniform, but it had other side effects, according to Lee. From its earliest years, the court consistently sided with patent holders, and it was able to do so "in part because the [U.S] Supreme Court took a hands-off approach to the subject during the new court's first two decades."

Lee discusses U.S. Supreme Court rulings from 2006-2008 in which the Court "stepped up its oversight of the Federal Circuit's work" under Chief Justice John Roberts and overruled patent-friendly decisions. And while the Federal Circuit "took some token steps to bring its decisions in line with Supreme Court precedents," it has "continued to exhibit a strong pro-patent bias, which has forced the Supreme Court to continue overturning pro-patent rulings from the court." Lee cites a recent patent ruling from Judge Richard Posner who opined that the "patent system had descended into 'chaos,'" and

contends that "breaking the Federal Circuit's monopoly on patent appeals may be the single most important step we can take to fix the patent system." He predicts that the "Federal Circuit looks likely to undermine other reforms undertaken by Congress, just as it has resisted the Supreme Court's efforts to bring balance to patent law."

NEW BIO BUSINESS VENTURES

BioFuels Company Inks Deal with Lufthansa to Build Algae-Based Production Facility

Australia-based biofuel company Algae.Tec Ltd. has announced an agreement with Lufthansa to build an aviation biofuels production facility in Europe. The airline carrier will provide 100 percent of the project's funds and will commit to a long-term "offtake agreement" of at least 50 percent of the crude oil produced at a set price. Algae.Tec will manage the facility and receive license fees and profits. The algae oil produced will fulfill the European Union Renewable Energy Directive and be certified according to the International Sustainability & Carbon Certification standard. The deal must be approved by both companies' boards, and a final feasibility report will be completed when the site has been chosen. *See Algae.Tec News Release*, September 19, 2012.

In a related development, the company has reportedly unveiled plans to raise $600 million by 2015 to build at least six production facilities in Australia, Brazil, Sri Lanka, and the United States. According to Algae.Tec Chair Roger Stroud, "We will be using different project finance structures for all of these projects and they'll all be roughly $100 million." He contends, "There's no shortage of people who will buy the fuel; both our biodiesel and jet fuel." The company's outlook improved on recent news that the European Commission decided to limit crop-based biofuels to 5 percent of transportation fuel, turning instead to the new generation of biofuels made from waste products, grasses, inedible plant parts or non-food feedstocks such as algae. *See Reuters*, September 24, 2012.

INVESTOR NEWS

Cancer Diagnostics Co. Raises $42.5 Million from Investors

Foundation Medicine Inc. has reportedly completed a $42.5-million Series B financing round that will help the company expand commercial operations, increase its laboratory capabilities and develop additional genomic profiling and information services. The cancer diagnostics company indicated from its Cambridge, Massachusetts, headquarters that its genomic assay for all solid tumors, FoundationOne™, has been ordered by more than 400 physicians in 16 countries since it was launched in June 2012. The company focuses on

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expanding treatment options for cancer patients by "matching each patient with targeted therapies that may be relevant to the molecular changes in their tumor." *See Foundation Medicine News Release*, September 20, 2012.

NuPathe Secures $28 Million from Private Stock Offering for Migraine Pain Patch

Specialty pharmaceutical company NuPathe has announced agreements to sell $28 million of securities with existing and new investors. This financing will apparently be used to advance the Conshohocken, Pennsylvania-based company's primary goal of gaining approval for its migraine patch. The company focuses on developing and commercializing branded therapeutics for diseases of the central nervous system.

According to CEO Armando Anido, "We believe this financing, combined with cost containment measures we expect to implement, will provide the financial resources necessary to fund our operations for approximately one year and, importantly, to obtain approval for NP 101." Series A stockholders will reportedly be entitled to elect three directors to the company's board; the closing is subject to certain conditions, including stockholder approval, although NuPathe has sought a waiver of this requirement from NASDAQ. *See NuPathe News Release*, September 25, 2012.

BUSINESS CLIMATE

Venture Capitalists Are Returning to Life-Sciences Investing

Reuters reports that a number of global venture firms have renewed their interest in the life sciences and health-care sectors, motivated by big acquisitions, U.S. laws speeding up certain drug approval processes and new products that have broadened the life-sciences definition. Venture funds invested $4.82 billion in biotechnology in 2011, an increase of 24 percent from 2010; medical-device investments increased 17 percent, and health-care services investment rose 41 percent. Another key development in the renewed interest are the investments that major pharmaceutical companies are making in early-stage companies, some have even created their own venture funds for this purpose.

Among the venture firms setting aside large sums with a life-sciences focus are Canaan Partners, $600 million, Flagship Ventures, $270 million, and New Enterprise Associates, $2.5 billion. Because the field does not produce quick returns, these investments are typically cyclical, but efforts by U.S. lawmakers and regulators to accelerate the drug approval process particularly for breakthroughs on life-threatening diseases are giving investors hope of quicker returns. Among the new products that have been added to the life-sciences portfolio are those applying information technology to certain health-care problems, such as programs allowing patients to compare the costs of

medical procedures, automated appointment booking, DNA testing, medical records, and health-care related apps. *See Reuters*, September 24, 2012.

Moody's Claims "The Worst Is Over" for Pharmaceutical Companies Facing Patent Cliff

Moody's Investor Services has reportedly revised its outlook for the global pharmaceutical industry and upgraded it to stable, apparently anticipating that earnings will rebound in 2013 with the slowdown in patent expirations, characterized by many industry observers as the "patent cliff." Moody's had given the industry a negative credit rating since 2007. According to a Moody's spokesperson, "The stable outlook reflects our view that the worst of the industry's blockbuster patent expirations has passed. Although industry earnings will still be affected by very recent patent expirations, earnings for large, branded (drugmakers) will reach a trough in late 2012 and rebound in 2013."

He cautioned, however, that "a difficult regulatory approval environment for new products," continues to challenge the industry, along with efforts in other countries to contain costs and the increasing use of generic drugs. Spending on brand-name pharmaceuticals is reportedly projected to increase from $596 billion in 2011 to $615 billion in 2016, while global spending on generics is expected to increase from $242 billion to $430 billion by 2016. *See Forbes*, September 25, 2012.

Study Shows R&D Spending in Biotech Has Rebounded

Accounting and consulting group BDO USA has released a report based on information from publicly traded companies' 10K U.S. Securities and Exchange Commission forms showing that research and development (R&D) spending in the biotechnology sector grew 5 percent in 2011, with biotech companies spending, on average, $50 million in 2011, an increase of $3 million invested in R&D in 2010. Other BDO USA findings include (i) biotech companies have shown an increase in their employee base, with larger companies growing their workforce 16 percent and smaller companies increasing payrolls by 3 percent; (ii) the increasing reliance on innovative business models, including virtual participation by outside specialized contractors and consultants to address specific needs; (iii) decreased spending per employee; (iv) an increase among larger companies spending cash generated from operations to fund R&D, with smaller companies turning to capital markets for funding; and (v) across-the-board losses for 2011, but steady financial liquidity as firms "continued to show signs of prudence in fiscal policy and cash management." *See BDO USA Press Release*, September 19, 2012.

Biotech Crops Responsible for $78.4 Billion Increase in Global Farm Income

According to a news source, research conducted by PG Economics Ltd. claims that biotech crops have increased global farm income by $78.4 billion during the period 1996-2010. Less acreage is needed to produce more corps, and pesticide spraying has apparently been reduced by 438 million kg over 15 years. PG Economics Director Graham Brookes, speaking during a press briefing in Hyderabad, also noted that crop biotechnology has significantly reduced the release of greenhouse gas emissions from agricultural practices. *See The Hindu Business Line*, September 25, 2012.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FTC Conducts Workshop on Competition and Safety in Pet Meds Industry

The U.S. Federal Trade Commission (FTC) conducted a day-long **workshop**, October 2, 2012, "to examine competition and consumer protection issues in the pet medications industry." Currently pending before the House Subcommittee on Health, a bill (**H.R. 1406**) introduced in April 2011 by Representative Jim Matheson (D-Utah) would require FTC to issue rules mandating pet medication prescription portability, which would fundamentally change the way such products are sold in the United States. FTC seeks stakeholder input on issues that would affect a $7-billion-a-year industry and has extended the public comment period to November 1.

An early step in FTC's investigation, the workshop provided a forum for widely divergent views as veterinary professional advocates and representatives of the animal health industry addressed current practices limiting the distribution of pet medications and the potential impact of a change that would allow consumers to purchase the drugs from a full range of providers and retailers. According to veterinary representatives, (i) retaining the status quo ensures drug safety and efficacy, (ii) pet medication pricing is currently competitive, and (iii) prescription portability is already required under veterinary ethical rules and some state laws. They claimed that the proposed legislation was nothing more than "a solution in search of a problem."

Counsel for generic drug manufacturers asserted, to the contrary, that portable prescriptions were essential to the development of more competitive pricing. Online pharmacy representatives claimed that their primary concern involves an inability to acquire pet medications from the manufacturers and their consequent shortages, as opposed to lack of prescription portability. Compounding pharmacists agreed with that assessment, noting that an inability to obtain drugs from manufacturers limited their ability to compound drugs not otherwise available in the marketplace. Major retailers asserted that restricting distribution to veterinarians raises consumers' costs, creates a potential conflict of interest for the prescribing veterinarian and

impairs convenience for "one-stop-shoppers" unable to purchase pet medications from retail pharmacies.

The American Society for the Prevention of Cruelty to Animals took the view that prescription portability would reduce costs to consumers, thereby increasing animal health and encouraging pet adoption from shelters.

With much of the evidence cited in support of the workshop participants' positions anecdotal or speculative, FTC also turned to evidence from the contact lens industry, which has operated under similar prescription portability legislation since 2003. This evidence was also unavailing given acknowledgement from panelists about a lack of adequate empirical evidence whether contact lens portability resulted in increased safety risks to consumers or lower prices.

The public comment period provides an important vehicle for stakeholders to ensure that FTC is evaluating full and reliable evidence on these issues. The Commission has posted on its **Website** the hundreds of comments already received and will place workshop submissions and PowerPoints® there to help stakeholders identify specific points to address. Agency officials indicated that the comments could inform FTC's report on the matter and will be used by lawmakers and regulators as they develop further regulatory, legislative or enforcement responses. This report was prepared by Shook, Hardy & Bacon Attorney Scott DuPree who attended the hearing. Contact him at **sdupree@shb.com**, or 816-474-6440, for further information or questions. *See FTC News Release*, September 19, 2012.

LITIGATION

Federal Court Addresses Spoliation Issues on Remand in *Hynix v. Rambus*

On remand from the Federal Circuit Court of Appeals, a federal district court in California has reversed its determination that Rambus, Inc. did not spoliate evidence by shredding hundreds of boxes in the months preceding its implementation of a strategy to aggressively protect its technology patents. *Hynix Semiconductor Inc. v. Rambus, Inc.*, No. C-00-20905 RMW (U.S. Dist. Ct., N.D. Cal., San Jose Div., decided September 21, 2012). Additional details about the case and the Federal Circuit's ruling in a companion suit appear in Issue **14** of this *Bulletin*.

The court issued new findings of fact and determined that the collateral estoppel doctrine required it to find, as the Federal Circuit had ruled, that the shredding occurred after litigation was reasonably anticipated. While the court found that Rambus acted in bad faith or at least willfully and that Hynix was prejudiced thereby, it refused to apply the unclean hands doctrine as a complete defense to Rambus's patent-infringement claims. According

to the court, the evidence did not show that Rambus knew that particularly damaging documents or emails were destroyed or specifically altered, hid or destroyed adverse evidence.

The court concluded, "[T]he sanction most commensurate with Rambus's conduct and which addresses the above concerns is to strike from the record evidence supporting a royalty in excess of a reasonable, non-discriminatory royalty. Such a remedy recognizes that Rambus's patents have been determined to be valid while at the same time recognizing that Rambus's spoliation of evidence should preclude it from entitlement to a royalty that places Hynix at a competitive disadvantage."

The court ordered the parties to brief the issue of "what a reasonable, non-discriminatory royalty rate would be with respect to the patents-in-suit." Hynix's supplemental brief must be filed by October 12, 2012, and Rambus's response must be submitted by October 26.

French Company Prevails in Dispute with FDA over Drug-Classification Ruling

A federal court in the District of Columbia has determined that the Food and Drug Administration (FDA) erred when it classified a combination drug-device product as primarily a drug, thus subjecting its French manufacturer to more burdensome regulatory requirements. *PREVOR v. FDA*, No. 1:11-cv-01187-RMC (U.S. Dist. Ct., D.D.C., decided September 25, 2012). Thus, the court granted the plaintiff's motion for summary judgment and vacated FDA's decision to designate the product as "a drug-device combination product with a drug primary mode of action."

The product, Diphoterine™ Skin Wash (DSW), was developed to mitigate chemical burns in industrial workplaces. It consists of a canister that sprays a solution at pressure on the skin to physically and mechanically remove splashes of acids and bases by washing them away. The solution of 96 percent water and 4 percent diphoterine then neutralizes and dilutes the chemicals. The manufacturer sought a request for designation from the FDA seeking confirmation that "DSW is a device to be regulated by the Center for Devices and Radiological Health." It has been marketed outside the United States as a device since 1996 and is registered or licensed as a medical device in Australia, Brazil, Canada, and Europe. FDA concluded that the product is a combination of a device and a drug and that the drug constituent part of DSW "provides the greater contribution to the overall therapeutic effect," thus justifying regulation as a drug.

According to the court, FDA failed to provide a "qualitative analysis" or cite "scientific information" on which it relied and stated only that "Since this liquid achieves its primary intended purposes, at least in part, through chemical action, it does not meet the definition of device." Because the statute distinguishes drugs from devices in combination products by refer-

ence to a "primary mode of action," the court agreed with the manufacturer's argument that "FDA now prevents a device from having even a *de minimus* chemical effect because the 'at least in part' or 'even in part' language is so encompassing."

In this regard, the court noted, "FDA treated *any* purpose of DSW as a *primary* intended purpose, contrary to the more limited language of the statute and the agency's distinction between primary and secondary in prior precedent." The court further stated, "FDA treated achievement *even in part* of *any* purpose through chemical action as achievement of a primary intended purpose through chemical action. There may be solid scientific reasons for FDA's new approach but these remain unexplained, at least without defining 'primary' in a manner consistent with the law."

ACLU Weighs In on Patentability of Human Genes in *Myriad Genetics*

American Civil Liberties Union (ACLU) attorneys representing the petitioners in *The Association for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398 (U.S., docketed October 1, 2012), have filed their petition for review before the U.S. Supreme Court. Information about the Federal Circuit Court of Appeals ruling from which the petition has been filed appears in Issue 41 of this *Bulletin*. The Federal Circuit reaffirmed its earlier ruling on the patentability of human genes after remand from the U.S. Supreme Court for consideration in light of *Mayo Collaborative Services v. Prometheus, Inc.*, 132 S. Ct. 1289 (2012).

The petitioners ask (i) "Are human genes patentable?"; (ii) "Did the court of appeals err in upholding a method claim by Myriad that is irreconcilable with this Court's ruling in *Mayo*?"; and (iii) "Did the court of appeals err in adopting a new and inflexible rule, contrary to normal standing rules and this Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), that petitioners who have been indisputably deterred by Myriad's 'active enforcement' of its patent rights nonetheless lack standing to challenge those patents absent evidence that they have been personally threatened with an infringement action?" A response is due October 31, 2012.

Law Professor Opines on Potential Consequences of Induced Infringement Case *Akamai*

Emory University School of Law Professor and Associate Faculty Dean Timothy Holbrook has authored an essay titled "The Potential Extraterritorial Consequences of *Akamai*," to consider the Federal Circuit Court of Appeals ruling allowing someone who induces others to infringe a patent to be held liable to the patent holder and abrogating a previous rule requiring a unitary infringer in order for a party to be liable for induced infringement under 35 U.S.C. § 271(b). Details about the court's split ruling appear in Issue 42 of this *Bulletin*.

According to Holbrook, the Federal Circuit "decoupled active infringement from § 271(a), meaning that infringement under § 271(b) is free-standing, and infringement is not defined by reference to other provisions of § 271. The decoupling also means that, as a statutory matter, the court has removed the territorial constraints from active inducement." His essay elaborates on that extraterritorial expansion and asks, among other matters, whether a U.S. patent is infringed where "a party outside of the United States actively induces someone to perform the steps of the method outside of the United States." He contends that "this cannot be the case," given that patents are creatures of national law and generally have no extraterritorial effect. Still, less extreme hypotheticals could, in Holbrook's view expand the law's extraterritorial reach under *Akamai*.

NEWS BYTES

U.S. Health and Human Services Secretary Kathleen Sebelius **delegates** authority to the Food and Drug Administration (FDA) to determine whether clinical trial information was not submitted to the Clinical Trial Registry and Results Data Bank as required by law or "was submitted but is false or misleading in any particular." FDA will provide the responsible party with an opportunity to remedy non-compliance.

The U.S. Patent and Trademark Office and European Patent Office launch the early publication of a classification system intended to "speed the patent granting process for applications to both Offices. The **Cooperative Patent Classification** (CPC) system and finalized CPC definitions are now available in advance of the January 1, 2013, official launch." The system involves a common classification system for technical documents in certain patent applications for use by both offices in the patent granting process.

The U.S. Patent and Trademark Office is **implementing** a law school patent pilot program through which participants "may file an application for a *pro bono* client of the law school clinic and that applicant's application may be advanced out of turn (accorded special status) for examination." Each school would be allotted up to two applications to be examined out of term per semester, and the total number of applications to be examined out of turn is limited to 64 per year.

The U.S. Patent and Trademark Office **extends** to October 22, 2012, the public comment period "regarding possible adjustments to trademark application filing fees." The initial notice of inquiry appeared in the August 16, 2012, issue of the *Federal Register*.

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The U.S. Patent and Trademark Office extends to November 5, 2012, the public comment period "regarding a potential legislative change to amend the first filing deadline for Affidavits or Declarations of Use or Excusable Nonuse under Sections 8 and 71 of the Trademark Act. The change would require Congress to amend the Trademark Act, and the USPTO is interested in receiving public input on whether and why such an amendment is or is not favored." The initial request for public comment appeared in the August 16, 2012, issue of the *Federal Register*.

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