Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

U.S. Supreme Court Issues Ruling on Patentability of Human Genes

The U.S. Supreme Court has determined that while human genes and the information they encode are not patent eligible, despite the effort required to isolate them, a synthetically created DNA strand—complementary DNA—that is not naturally occurring may be patent eligible. ***Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398 (U.S., decided June 13, 2013)**. Details about the Federal Circuit decision that the Court affirmed in part and reversed in part appear in Issue **41** of this *Bulletin*.

According to the Court, "Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13." Because the location and order of the nucleotides existed in nature before Myriad found them, the Court determined that certain of its patents did not satisfy the Patent Act's § 101 inquiry. At stake in the litigation was Myriad's exclusive right to isolate these genes and develop medical tests useful for detecting mutations that "dramatically increase the risk of breast and ovarian cancer."

Researchers Conclude Costs of Litigation Growing in Relation to Benefits of Patent Protections

Economics, law and technology scholars affiliated with U.S. and German institutions have issued a **paper** that examines data on the costs of patent litigation, particularly as an upsurge in non-practicing entity (NPE) infringement suits have occurred in recent years, and on the licensing income, or "rents," collected by patent owners. John Turner, et al., "The Costs and Benefits of United States Patents," *Boston University School of Law, Law and Economics Research Paper*, June 12, 2013. They conclude that "costs exceed benefits overall and that the gap between costs and benefits has grown across time. Surges in the number of NPE lawsuits, lawsuits filed over Computers/Communications patents, and lawsuits brought against non-manufacturing, software and telecommunications firms contribute to the increase in the gap."

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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

Thermo Fisher Underwriters Exercise Option to Purchase

Waltham, Massachusetts-based Thermo Fisher Scientific Inc. has announced that the underwriters of its previously announced public offering of $2.2 billion of common stock have exercised their option to purchase an additional 3,859,649 shares at $85.50 per share. Proceeds will be used to fund a portion of the company's pending acquisition of Life Technologies Corp., according to a company news release. Thermo Fisher plans to settle the forward sale agreements at or around the time of closing, which is expected to occur in early 2014, the company reported. *See Thermo Fisher News Release,* June 11, 2013.

Biotech Set to Raise $86 Million in IPO to Support Cancer and IEM Products

Agios Pharmaceuticals, Inc. has filed a registration statement with the U.S. Securities and Exchange Commission indicating its intent to raise up to $86 million in an initial public stock offering (IPO). The Cambridge, Massachusetts-based biotech, which develops treatments for cancer and inborn errors of metabolism (IEM), reportedly plans to use the IPO proceeds to fund clinical development of its lead product candidates in cancer and IEM programs. *See Reuters.com,* June 11, 2013.

Neumedicines Receives $8.3 Million from BARDA for Radiation Sickness Drug

Pasadena-based Neumedicines Inc. has reportedly received $8.3 million from the Biomedical Advanced Research & Development Authority (BARDA) of the U.S. Department of Health and Human Services to continue development of HemaMax™ (recombinant human interleukin 12 or rHuIL-12) for hematopoietic syndrome of acute radiation sickness (HSARS). Neumedicines evidently plans to submit HemaMax™ for a Biologic License Application (BLA) under the U.S. Food and Drug Administration's Animal Rule (21 C.F.R. 601.90-95) for the treatment of HSARS and will use the funds to conduct animal studies comparing the effectiveness of HemaMax™ with granulocyte colony-stimulating factor (G-CSF) as well as assess the effectiveness of a combination of HemaMax™ and G-CSF as a treatment for HSARS.

"We have now received more than $50 million from BARDA to support the development of HemaMax™ for HSARS," said Neumedicines President and CEO Lena Basile. "Our studies in non-human primates have shown that a single, low-dose, subcutaneous injection of HemaMax™ at 24 hours after exposure to lethal amounts of radiation (LD90) increased survival by up to 40%, without any supportive care or antibiotics. We also have shown in first-in-human and Phase 1b studies that HemaMax™ at a dose equivalent to the efficacious non-human primate dose is safe in healthy volunteers."

Basile reported that Neumedicines also intends to use the funds to explore the use of HemaMax™ on a pre-emergency use authorization basis and to develop it as a hematological adjuvant therapy for cancer patients. "HemaMax™ provides concomitant anti-infectivity and anti-tumor responses that are additive to the primary cancer therapy. We don't know of any other drug with these multifunctional properties," said Basile. *See BusinessWire.com,* June 10, 2013.

Diagnoplex Secures $1.4 Million to Develop Colorectal Cancer-Screening Test

According to Diagnoplex SA and Debiopharm Diagnostics SA, part of the Lausanne, Switzerland-based Debiopharm Group™, Diagnoplex has received $1.4 million in a financing round led by Debiopharm. The company plans to use the funds to obtain CE (European Conformity) marking for Colox®, its minimally invasive blood test for colorectal cancer screening. Diagnoplex reported that it also plans to use the funds to prepare a comparative clinical trial for Colox.

"The early screening of colon cancer is key. It is tomorrow's personalized medicine. We are proud to contribute to the progress of such an entrepreneurial and innovative company such as Diagnoplex," said Debiopharm Group Board Delegate Thierry Mauvernay. Diagnoplex CEO and founder Stavros Therianos, said "We are very pleased to announce the renewal commitment of Debiopharm, who led this round. This financing will allow Diagnoplex to continue its development and to [progress] in establishing a collaboration for the commercialization of its diagnostic test." *See Diagnoplex SA News Release,* June 7, 2013.

Dermatology Biotech Receives $35 Million

Dermira, a Redwood City, California-based developer of dermatology therapies, including the acne treatment lemuteporfin, has raised $35 million in a Series B financing round. The funding came from new investor Maruho Co., Ltd., a Japanese dermatology company, and existing investors Bay City Capital, New Enterprise Associates and Canaan Partners. "This financing, with the addition of Maruho and their expertise in global dermatology, demonstrates Dermira's continued progress in the development of innovative, novel compounds in areas of high patient need," said Dermira CEO Tom Wiggans. "This support from premier investors and partners further underscores the opportunities for innovative new therapies in dermatology around the world." *See Dermira News Release,* June 11, 2013.

Biofuel Maker Raises $29.9 Million for Production Facility

Camarillo, California-based biofuel technology developer Cool Planet Energy Systems Inc. has secured $29.9 million of an anticipated $100-million Series

D financing that will reportedly fund construction of the company's first commercial plant. Cool Planet has developed a biomass-to-fuel process, which the company says can produce high-octane gasoline, jet fuel or diesel at a cost of less than $1.50 per gallon.

"We are very pleased to have completed this early close which includes investments by all of our existing investors along with some high quality new investors," said Cool Planet CFO Barry Rowan. "We remain very encouraged by the response to our ongoing fundraising efforts in the U.S. and globally, and fully expect to achieve our goal of raising a minimum of $100 million in this round." CEO Howard Janzen added, "With today's announcement, we continue to lay the foundation to deliver on our objectives of producing renewable transportation fuels, a cleaner environment, and the improvement of agriculture." *See Cool Planet Energy Systems Inc. News Release,* June 7, 2013.

BUSINESS CLIMATE

Biopharmaceutical Companies Have 215 Heart Disease/Stroke Drugs in R&D Pipeline

According to a new Pharmaceutical Research and Manufacturers of America (PhRMA) **report**, U.S. biopharmaceutical companies have 215 medicines under development for the treatment of heart disease and stroke. The medicines, which are currently either in human clinical trials or undergoing U.S. Food and Drug Administration review, aim to treat or prevent these two leading causes of death in the United States by addressing heart failure, lipid disorders, stroke, and hypertension. PhRMA President and CEO John Castellani noted that many of these pipeline drugs use cutting-edge technologies including gene therapy and genetic engineering. He said, "These promising new approaches offer great hope to better prevent and treat heart diseases. They also hold the potential of helping to control costs within our healthcare system, as reflected in a growing body of evidence showing that medicines—including those for heart disease—can help control overall healthcare costs." *See PhRMA Press Release*, June 12, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Pharmacy and Hospital Interests Present Comments on Proposed Compounding Bill

Proposed legislation (**S. 959**) that would give the U.S. Food and Drug Administration (FDA) the authority to oversee compounding pharmacies that ship products across state lines has generated comment from a broad array of stakeholders. Additional details about the legislation, which was approved unanimously in late May 2013 and reported in the nature of a substitute by

the Health, Education, Labor and Pension Committee, appear in Issue 56 of this *Bulletin*.

On behalf of the American Society of Health-System Pharmacists and American Hospital Trusts, the Pew Charitable Trusts submitted comments supporting the increase in oversight but calling for changes that would strengthen the bill. Among other matters, these groups call for expanding the bill's application to "large-scale, *intra*state sterile compounding and large-scale non-sterile compounding," warning that by "reducing FDA's authority over certain state-regulated pharmacies, the law may encourage the growth of these types of compounding."

Meanwhile, compounding pharmacies have launched a **campaign** to stop the bill, claiming that it will "threaten the health and safety of men, women, children and pets." They claim that the proposed legislation would give FDA unprecedented authority over their operations and seek to distance themselves from operations such as the New England Compounding Center, purportedly linked to a Hepatitis A outbreak, which "was in reality distributing many of its medications without the pharmacist-prescriber relationship, and therefore was acting as a manufacturer/wholesaler." *See MyMedsMatter.com*, June 12, 2013.

FDA Seeks Comments on De-Identified and Masked Data

The U.S. Food and Drug Administration (FDA) has issued a **notice** seeking comments on "the proposed availability of de-identified and masked data derived from medical product applications." Calling for improved efficiencies and effectiveness in medical product development, the agency stated that making available "de-identified and masked clinical and preclinical data," could provide "scientific data that may be of value in the generation of new knowledge to facilitate innovation in the development and evaluation of critically needed medical products."

FDA has specifically requested comments on the following: (i) what factors should be considered in masking study data; (ii) what limitations, if any, should be placed on the agency's ability to make masked data available; (iii) are there additional factors FDA should consider in de-identifying data aside from removing names and other information that identify patients or research subjects; (iv) would regulatory changes facilitate implementation of such a proposal, and if so, what changes would be most useful; and (v) in what situations would disclosing masked data be most useful to advance public health. FDA will accept comments until August 5, 2013. *See Federal Register,* June 4, 2013.

Lab Trade Association Presses FDA on Plan to Regulate Laboratory Developed Tests

The American Clinical Laboratory Association (ACLA) has submitted a **citizen petition** to the Food and Drug Administration (FDA), asking the agency to "refrain from issuing draft or final guidance or a proposed or final rule purporting to

regulate LDTs [laboratory developed tests] as devices" and to confirm "that LDTs are not devices" under the Food, Drug, and Cosmetic Act. The trade organization argues that FDA lacks the authority to regulate LDTs.

ACLA explains that LDTs "are in vitro assays that clinical laboratories develop, validate, and perform as testing services. Laboratories create LDTs by establishing procedures for performing the tests with reagents and laboratory equipment. The laboratory receives test orders for specific patients, performs the test according to its own procedures, and reports the test results to the authorized persons who ordered them." According to ACLA, because LDTs are not distributed commercially, "LDTs thus differ from in vitro diagnostic test kits, which commonly are products containing all or most of the components needed to perform a test, such as reagents and equipment, that are packaged and commercially distributed to laboratories, other providers, and, in some cases, consumers."

The petition notes that FDA has signaled its intent to regulate LDTs despite Congress's July 2012 enactment of a Food and Drug Administration Safety and Innovation Act provision prohibiting FDA from issuing any draft or final guidance on the regulation of LDTs without providing 60 days' notice to two congressional committees. Stating that "LDTs are critical to timely and effective patient care," . . . "reflect the latest research and scientific developments and allow rapid diagnosis and assessment of emergent infectious diseases, among other diseases and conditions," ACLA contends that "FDA regulation of LDTs as devices would preclude them from serving these critical public health purposes." In ACLA's view, laboratory oversight provided by the Clinical Laboratory Improvement Act is sufficient to ensure the continuing validity and reliability of LDTs.

India Holds Out Among Countries Requiring Transparency in Industry Payments

According to a news source, while many countries have instituted disclosure obligations on health-care companies, often pharmaceutical and medical-device manufacturers, that provide benefits in kind or cash to health-care professionals, including physicians, India has resisted calls from parliamentary committees, the Medical Council of India and some physicians to adopt transparency requirements. France is apparently the latest country to enact disclosure obligations as part of its Strengthening of Health Protection for Medicinal and Health Products law. It will reportedly apply to all agreements between health-care professionals and companies, such as R&D contracts, contracts for clinical trials or observational studies, consultancy agreements, and reimbursements for the costs of medical and scientific conferences, and to every benefit exceeding €10 in value.

A U.S. law that takes effect in August 2013 will make publically available records of all payments that pharmaceutical, medical device, biological, or medical supply companies make to physicians and other health-care professionals. A public Website will begin posting the data in September 2014. The American Medical Association slated a session during its June 2013 annual conference and

prepared a **brochure** to explain the law's implications and requirements. *See The Times of India*, June 10, 2013.

LITIGATION

SCOTUS Sides with FTC in Reverse Payment Deals

A divided U.S. Supreme Court has determined that patent-infringement settlement agreements requiring the patentee to pay the claimed infringer millions of dollars to delay producing the patented product until the patent term expires may violate antitrust laws even if the "reverse payment" settlement agreement's "anticompetitive effect falls within the scope of the exclusionary potential of the patent." ***FTC v. Actavis, Inc.*, No. 12-416 (U.S., decided June 17, 2013)**. So ruling, the Court reversed an Eleventh Circuit dismissal of antitrust claims brought by the Federal Trade Commission (FTC) in the context of a reverse payment agreement between a pharmaceutical company and producers of generic drugs similar to the patented drug.

FTC alleged that the generic companies unlawfully agreed to abandon their patent challenges, refrain from producing and marketing their low-cost generics and share the branded drug maker's monopoly profits. Because the agreement extended only until the patent would expire, the lower courts determined that the settlement was immune from an antitrust challenge. While the U.S. Supreme Court declined to hold that these agreements are presumptively valid or invalid, it ruled that courts reviewing them should apply the "rule of reason," rather than a "quick look" approach. According to the Court, the form of settlement at issue, that is, the plaintiff agrees to pay the defendants many millions of dollars to stay out of its market, even though the defendants do not have any claim that the plaintiff was liable to them for damages, "is unusual" and "there is reason for concern that settlements taking this form tend to have significant adverse effects on competition."

The dissenting justices would simply have asked "whether the settlement gives [the patentee] monopoly power beyond what the patent already gave it." They argued that the majority's approach was "novel," lacked support in any statute and would "discourage the settlement of patent litigation."

En Banc Federal Circuit Issues Ruling on Appellate Jurisdiction over Patent Infringement Issues

The Federal Circuit Court of Appeals en banc has determined that parties may appeal the liability issues in a patent infringement action even if the bifurcated damages issues have not been tried and they involve claims of willfulness. ***Robert Bosch, LLC v. Pylon Mfg. Corp.*, Nos. 2011-1363, -1364 (Fed. Cir., decided June 14, 2013)**.

Shook, Hardy & Bacon L.L.P.

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

ISSUE 59 | JUNE 20, 2013

Seven of the nine judges concluded that the exception to the final judgment rule in 28 U.S.C. § 1292(c)(2) allowing an appeal to the Federal Circuit from a patent infringement judgment that is "final except for an accounting" included those actions in which a trial on damages is pending. The court examined the history of what is meant by patent-infringement "accounting" in legislation and court rulings to hold that a trial on damages is an accounting under § 1292(c)(2). Five of the nine judges concluded that an accounting also includes the determination of willfulness. Thus, the court remanded the matter to a Federal Circuit panel to consider the merits of the liability issues on appeal while proceedings on damages issues remain stayed before the district court.

NEWS BYTES

The U.S. Patent and Trademark Office (USPTO) **launches** a joint pilot project with the Korean Intellectual Property Office (KIPO) which will classify some of its patent documents using the Cooperative Patent Classification system. The offices will work together to identify the particular technologies for which filings have been active at KIPO, and the classification project will apply to the technologies identified. USPTO and the European Patent Office jointly manage the system.

The U.S. Patent and Trademark Office (USPTO) and the heads of the world's largest intellectual property offices **renew** "their commitment to develop the 'Global Dossier,' a system to simplify the viewing and management of applications filed in the IP5 [five largest intellectual property offices] Offices." The agreement came during a recent meeting in Silicon Valley. IP5 members are the USPTO, European Patent Office, Japan Patent Office, Korean Intellectual Property Office, and State Intellectual Property Office of the People's Republic of China.

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