Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Argument on Remand Scheduled in *Myriad Genetics*

The Federal Circuit Court of Appeals has scheduled briefing and oral argument in *Association for Molecular Pathology v. U.S. Patent and Trademark Office (Myriad Genetics)*, which the U.S. Supreme Court remanded for reconsideration in light of the Court's ruling in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). At issue is whether isolated DNA is patent eligible; additional details about the case appear in Issue 18 of this *Bulletin*. Briefs must be submitted by June 15, 2012, and the court will hear argument on July 20 as to this question: "What is the applicability of the Supreme Court's decision in *Mayo* to Myriad's isolated DNA claims and to method claim 20 of the '282 patent?" *See Bloomberg BNA Life Science Law & Industry Report*, May 4, 2012.

NIH to Fund Research on Shelved Pharma Compounds, Private Sector to Retain IP Rights

The National Institutes of Health (NIH) has entered a memorandum of understanding (MOA) with several large pharmaceutical companies under which the companies will provide government-funded researchers with selected material and information relating to compounds no longer under active development. The MOAs provide that the companies will retain any patent rights and the researchers will have rights to publish their findings. The company and the researcher will then negotiate commercial development opportunities and rights, as needed.

The pilot program, referred to as "Discovering New Therapeutic Uses for Existing Molecules," will reportedly provide $20 million in fiscal year 2013 for eight to 10 initial grants and provide at least $20 million in additional funding in each of the following two years. According to a news source, if a new drug shows signs of being effective, the company that owns it would be expected to fund final testing and work out a royalty agreement for subsequent sales. While the federal treasury will not benefit financially from the arrangement, unless an "intramural" NIH researcher is a grant recipient, federal officials are

apparently calling the program a creative way to develop potentially breakthrough treatments that would otherwise not be developed given constraints on resources. *See CQ Healthbeat News*, May 3, 2012.

INVESTOR NEWS

Eleven Biotherapeutics Secures $20 Million for Dry-Eye Drug Development

Focused on developing novel protein-based drugs, Eleven Biotherapeutics Inc. has reportedly secured $20 million in Series A equity financing, expanding the total raised to $45 million. JAFCO Co. Ltd. joined the round with a $10-million investment, which was matched by existing investors Third Rock Ventures and Flagship Ventures.

According to the Massachusetts-based company, the proceeds will be used to advance its lead drug candidate "EBI-005," a "novel interleukin-1 receptor antagonist" poised to enter clinical development for the treatment of dry-eye syndrome later this year. "This financing provides us with a strong financial foundation and firmly validates our investors' enthusiasm for Eleven's ability to develop novel, best-in-class protein therapeutics," said Eleven's CEO Abbie Celniker. *See Eleven Biotherapeutics Press Release*, May 8, 2012.

Egalet Lands $14.3 Million to Develop Abuse-Resistant Opioids

Egalet Ltd., a Pennsylvania-based pharmaceutical company focused on developing abuse-resistant pain medications, has reportedly raised $14.3 million in Series B financing. Noting that CLS Capital joined existing investors such as Atlas Venture, Omega Funds, Sunstone Capital, and Index Ventures, the company also announced that Bob Radie has been appointed president and CEO. "With the funds raised and Bob's appointment, Egalet is well positioned to move through the final stage of development with its lead abuse-resistant pain programs," said Board Chair Jean-Francois Formela. The company claims to have pioneered a gradual tablet-erosion delivery technology that allows controlled drug releases which can prevent abuse. *See PRNewswire,* May 7, 2012.

Retrophin Completes $4-Million Series A Financing Round for Rare-Disease Drug Candidates

New York-based Retrophin LLC has reportedly completed a $4-million Series A financing round to advance its pipeline of rare and life-threatening disease drug candidates. Led by MSMB Capital, the financing will help Retrophin enroll patients in a study of "RE-021" for the treatment of focal segmental glomerulosclerosis, a form of kidney disease named for the scarring that can be found in the kidneys of affected patients. "With our Series A complete, we're in a position to advance our lead compound, RE-021, through our proof

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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of concept, as well as to continue development of RE-001 for the treatment of Duchenne Muscular Dystrophy," said Retrophin CEO Martin Shkreli. *See Retrophin Press Release,* May 7, 2012.

Axion BioSystems Raises Funds to Develop Drug-Screening Technology

Axion BioSystems has reportedly raised $3.2 million as part of a $3.5-million planned round, according to its U.S. Securities and Exchange Commission filing. The company is developing and marketing instrumentation designed to improve drug screening and reduce the need for animal testing by giving scientists better knowledge of neural and cardiac cell behavior. In 2010, the Georgia-based biotech company evidently raised more than $2 million from private investors. *See Atlanta Business Chronicle*, May 9, 2012.

Cadence Biomedical Closes Oversubscribed Financing Round for Medical Device Production

Cadence Biomedical, which produces medical devices that help the severely disabled walk, has reportedly closed an oversubscribed $1.1-million Series A2 financing led by HealthTech Capital. Additional investors include Sand Hill Angels, Tech Coast Angels, ACE Fund, Frontier Angel Fund, WINGS, Alliance of Angels, and Keiretsu Forum Northwest.

According to the Seattle-based company, the financing will help it produce and market Kickstart™ Kinetic Orthosis, a device that uses a system of pulleys and springs that capture energy "during the beginning of a step and then return it at just the right moment to help propel the user forward and lift the leg in preparation for the next step." HealthTech's co-founder and Managing Director Don Ross noted, "In people with disabilities, Kickstart significantly improves walking and mobility and endurance, and Kickstart wearers are excited about their new independence and increased activity levels." *See Business Wire,* April 26, 2012.

Austrian Biotech Signs Financing Deal with Switzerland's BB Biotech

Intercell, an Austrian biotech vaccine company, has reportedly entered a financing deal with Switzerland's BB Biotech, a global biotech-company investor. According to Intercell, the investment through a fully owned subsidiary consists of a €20-million ($26.1 million) secured loan and a commitment to invest €5 million as part of a proposed equity private placement. According to Intercell, the company is in discussions with specialized health care investors regarding proposals for an additional investment of €10 to €15 million as part of the private placement. "The BB Biotech investment and the private placement, which should close before the end of May, are expected to secure Intercell's funding needs into financial self-sustainability," Intercell said. *See Intercell Press Release,* May 7, 2012.

BUSINESS CLIMATE

Biotech Jobs Post Significant Increase in Q1 of 2012

According to the number of advertised openings in the biotech sector appearing in online job databases, the pace of hiring in the first quarter of 2012 has significantly overtaken the last quarter of 2011. Monster.com reportedly had 493 openings at the 25 largest biotechnology companies as compared to 264 available at the end of 2011. Still, several major pharmaceutical and life sciences companies have apparently indicated they will be restructuring and reducing their work forces to save millions in overhead in the next few years. *See Nature Biotechnology*, May 2012.

Growth in Global Biofuels Industry Noted in New Report

In a report prepared for the Global Renewable Fuels Association, John Urbanchuk of the environmental and natural resource management consulting firm Cardno Entrix suggests that the global biofuels industry has recently made a "significant contribution to the individual economies of producing countries and to the global economy as a whole."

In the May 3, 2012, report, Urbanchuk asserts that "key drivers" for the global biofuels industry include the desire to (i) expand alternative energy sources, (ii) reduce dependence on volatile world oil and petroleum prices, (iii) create new revenue for farmers, and (iv) stimulate agriculture production. The study examines global production trends in ethanol and biodiesel, estimates the global economic footprint of the biofuels industry and identifies new and emerging markets, including Asia and Africa.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Senate Committee Approves Bill Aimed at Improving Safety of Drugs, Devices for Kids

The U.S. Senate's Health, Education, Labor and Pensions Committee has reportedly approved a bill (S. 2289) aimed at making children's medications and devices safer. Introduced by Senator Jack Reed (D-R.I.), the "Better Pharmaceuticals and Devices Act of 2012" is part of a larger package that includes provisions reauthorizing user fees for drugs, medical devices, generics, and biological products. It will be forwarded to the Senate for a vote. Its goals include (i) ensuring that pediatric studies are planned earlier in the drug-development process and that they are completed; (ii) increasing the transparency of completed, pending and declined children's studies; and (iii) permanently reauthorizing advisory committees, programs and grants addressing pediatric drugs and devices. *See Becker's Hospital Review,* May 4, 2012.

European Commission Study Recommends Changes to Medical Device and Drug Laws

The European Commission has issued a report that analyzes the European Union's (EU's) REACH regulation, which addresses the registration, evaluation, authorization and restriction of chemical substances, and identifies overlap with other EU laws. Among other matters, the report includes recommendations for more efficiently regulating potential risks posed by pharmaceuticals and medical device components. If adopted, the proposed changes would exempt medical devices altogether from REACH due to industry concerns that "under REACH the risks of using a substance in a medical device could be considered too high, while under the Directives on medical devices the risks of the use are accepted, because of the crucial function the device performs."

Prepared by consultant Milieu Ltd., the report also recommends that a mechanism be provided to gather data on potential environmental hazards of medicinal products throughout their life cycles. Medicinal products are currently exempt from REACH, and other applicable regulatory directives apparently do not require human health and environmental risk assessments. Noting that only veterinary medicinal products can be refused authorization in order to protect the environment, the report recommends that this protection be extended to medicinal products for human use. The European Commission was required under Article 138(6) of REACH to carry out a review by June 2012 to determine whether the regulation needed amendment "to avoid overlaps with other relevant Community provisions. On the basis of that review, the Commission may, if appropriate, present a legislative proposal."

LITIGATION

JPML Rules Patent Law Reforms Do Not Limit Its Authority to Consolidate Cases

The Judicial Panel on Multidistrict Litigation (JPML) has determined that reforms adopted under the America Invents Act (AIA) do not limit its authority to centralize litigation filed in federal courts for coordinated or consolidated pretrial proceedings. *In re: Bear Creek Techs., Inc., ('722) Patent Litig.*, MDL No. 2344 (J.P.M.L., decided May 2, 2012). The issue arose from a patent holder's request that JPML centralize 14 infringement actions involving its telecommunications patent. One of the defendants argued that part of the AIA, 35 U.S.C. § 299(b), limits JPML's authority to do so.

That section provides, "For purposes of this subsection, accused infringers may not be joined in one action as defendants or counterclaim defendants, or have their actions consolidated for trial, based solely on allegations that they each have infringed the patent or patents in suit." Rejecting the defendant's argument, JPML notes that its multidistrict litigation (MDL) transfer authority and the AIA's joinder provision "operate under decidedly different standards."

MDL transfer does not join defendants, and each separate action must be remanded to the originating court at the close of pretrial proceedings. In contrast, the AIA does not address pretrial proceedings, focusing instead on consolidation for trial.

JPML also observes that the AIA was adopted after the cases at issue were filed, and if Congress had intended to limit its transfer authority "it would have done so in a more direct fashion. . . . In the recent past, when Congress has limited the Panel's authority to transfer a certain category of actions, it has done so explicitly. For instance, pursuant to a provision of the Class Action Fairness Act, Section 1407 transfer of an action removed pursuant to the statute's 'mass action' provisions is prohibited unless a majority of plaintiffs so request." JPML further rejected the claim that centralization "will lead to a flood of MDL patent filings by non-practicing entities seeking to execute an 'end run' around the AIA's new joinder requirements."

According to JPML, "We do not accept this assertion as being a sufficient reason to deny centralization in this litigation. Centralization of any litigation—including patent cases—is not automatic, and will necessarily depend on the facts, parties, procedural history and other circumstances in a given litigation." Because the cases presented common questions of fact, and centralization "will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation," JPML ordered that the cases be transferred to the District of Delaware.

Federal Circuit Confirms Jurisdiction over Malpractice Claim Against Patent Law Firm

The Federal Circuit Court of Appeals has determined that a patent holder did not introduce sufficient evidence to prove that hypothetical alternative patent claims would have been patentable and thus, as a matter, of law, could not show that the law firm which prepared his patent committed malpractice by drafting the claims "so narrowly as to offer virtually no protection against competitors, resulting in lost-sale damages." ***Minkin v. Gibbons, P.C.*, No. 2011-1178 (Fed. Cir., decided May 4, 2012)**. So ruling, the court affirmed the district court's grant of the defendant's motion for summary judgment.

The court also confirmed that its precedent recognizes its jurisdiction "in patent attorney malpractice cases such as this one, in which the plaintiff is required to establish that, but for attorney negligence, he would have obtained valid claims of sufficient scope that competitors could not easily avoid." Concurring, Judge Kathleen O'Malley reiterated her call for the court to re-examine its precedent on this issue, opining that it is incorrect and inconsistent with controlling U.S. Supreme Court case law.

NEWS BYTES

The Food and Drug Administration conducts a **public hearing** on draft guidances pertaining to a pathway to approval for biosimilar products.

U.S. Representative Lois Capps (D-Calif.) introduces a bill (**H.R. 5341**) to improve post-market risk identification and analysis associated with medical devices. Titled "Sentinel Assurance for Effective Devices Act of 2012," the bill would also set a December 31, 2012, deadline for the Food and Drug Administration to release a final rule on the unique device identification system.

The U.S. Department of Agriculture's Advisory Committee on Biotechnology and 21st Century Agriculture schedules a **meeting** for May 29-30, 2012, in Washington, D.C. The agenda includes final reports from four working groups and "potential economic impacts on farmers from the escape of certain genetically engineered crops with functional traits."

The U.S. Patent and Trademark Office requests **comments** on its proposal to adjust certain patent fees for fiscal year 2012 "to reflect fluctuations in the Consumer Price Index (CPI)" as required under the patent statute. The fee adjustment calculations are based on a CPI increase of 2.9 percent.

The U.S. Patent and Trademark Office implements a **pilot program** "intended to reduce pendency and applicant costs when an information disclosure statement (IDS) is filed after payment of the issue fee. This pilot program will permit an examiner to consider an IDS after payment of the issue fee without the need to reopen prosecution, effectively obviating the need to pursue a request for continued examination (RCE)."

The U.S. Patent and Trademark Office (USPTO) requests **nominations** for two public advisory committees that review USPTO's policies, goals, performance, budget, and user fees with respect to patents and trademarks, respectively.

The Food and Drug Administration issues a **final rule** on sterility testing of biological products to provide biological product manufacturers greater flexibility and encourage "use of the most appropriate and state-of-the-art test methods for assuring the safety of biological products." The rule takes effects June 4, 2012.

In a non-precedential ruling, the Federal Circuit Court of Appeals determines that the America Invents Act, which retroactively extinguished "false-marking" claims filed by individuals on behalf of the government (in *qui tam* proceedings), does not violate the Takings or Due Process Clauses of the U.S. Constitution. ***Rogers v. Tristar Prods., Inc.*, No. 2011-1494, -1495 (Fed. Cir., decided May 2, 2012)**.

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UPCOMING CONFERENCES AND SEMINARS

The American Conference Institute's "3rd Advanced Forum on Biosimilars" will be held May 22-23, 2012, in New York City. Industry leaders will address the legal, regulatory and commercial aspects of "follow-on biologics," and a keynote address on implementing the biosimilar pathway will be presented by a Food and Drug Administration official.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

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