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 Says New Evidence Allowed in Section 145 Proceeding

The U.S. Supreme Court, in a unanimous opinion authored by Justice Clarence Thomas, has determined that 35 U.S.C. § 145, which allows a disappointed patent applicant to file a civil action against the U.S. Patent and Trademark Office director in lieu of filing a direct appeal to the Federal Circuit from the Board of Patent Appeals, does not limit the introduction of new evidence. ***Kappos v. Hyatt*, No. 10-1219 (U.S., decided April 18, 2012)**. Additional details about the case appear in **Issue 16** of this *Bulletin*. So ruling, the Court affirmed the Federal Circuit's decision to vacate a summary judgment granted to the director.

Essentially, the Court rejected the director's argument that administrative law principles "govern the admissibility of new evidence and require a deferential standard of review in a § 145 proceeding." According to the Court, these proceedings are not limited to the administrative record; rather, "the district court may consider new evidence [and w]hen the district court does so, it must act as a factfinder. In that role, it makes little sense for the district court to apply a deferential standard of review to [USPTO] factual findings that are contradicted by the new evidence." The Court also held that principles of administrative exhaustion do not apply to a § 145 proceeding. Still, the Court agreed with the Federal Circuit that "the district court may, in its discretion, 'consider the proceedings before and findings of the Patent office in deciding what weight to afford an applicant's newly admitted evidence.'"

Justices Sonia Sotomayor and Stephen Breyer concurred to suggest that district courts retain the authority "consistent with 'the ordinary course of equity practice and procedure,' to exclude evidence 'deliberately suppressed' from the [USPTO] or otherwise withheld in bad faith. For the reasons set out by the Court, an applicant has little to gain by such tactics; such cases will therefore be rare."

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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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U.S. Commerce Department Claims $5 Trillion of GDP Attributable to IP-Intensive Industries

According to a new report, intellectual property (IP)-intensive industries, such as computer and peripheral equipment, pharmaceutical and medicines, medical equipment, and semiconductor and other electronic components, were responsible in 2010, directly and indirectly, for 1 in 4 jobs in the United States and contributed more than $5 trillion to, or 34.8 percent of, the gross domestic product (GDP).

The report, "Intellectual Property and the U.S. Economy: Industries in Focus," was prepared by the U.S. Department of Commerce's Economics and Statistics Administration and the U.S. Patent and Trademark Office (USPTO). It starts from the premise, "The granting and protection of intellectual property rights is vital to promoting innovation and creativity and is an essential element of our free-enterprise, market-based systems."

For the first time, government researchers identified the most IP-intensive industries (75 out of 313) in the United States and then examined "both the important trends and economic characteristics of these highly IP-intensive industries and their meaningful contributions to the U.S. economy." They caution that the statistics reported "may tend to under-represent the broad impact of IP in the American economy," due to the reliance on IP "to some degree" by nearly all industries, and that they "may not fully reflect the long-run economic benefits and costs of IP in promoting innovation and productivity growth." Not intended to recommend any policy or to "directly advance particular policy issues," the report was developed to "promote a better understanding of the industries where IP plays a particularly important role."

Among other findings, the report notes that while "overall employment in IP-intensive industries has lagged other industries during the last two decades," growth in this sector outpaced others during the 2010-2011 economic recovery period and average wages compare well to other jobs. "Average weekly wages for IP-intensive industries were $1,156 in 2010 or 42 percent higher than the $815 average weekly wages in other (non-IP-intensive) private industries."

According to the report, "Patent- and copyright-intensive industries have seen particularly fast wage growth in recent years, with the wage premium in patent-intensive industries increasing from 66 percent in 2005 to 73 percent in 2010, and the premium in copyright-intensive industries rising from 65 percent to 77 percent." The data also apparently showed that merchandise exports from these industry sectors accounted for 60.7 percent of total U.S. merchandise exports.

NEW BIO BUSINESS VENTURES

China Sees New Stem Cell Joint Venture and Capital Investment in Cord Blood Bank

China Biotech Group has announced a joint venture with China Stem Cell to launch a cancer cell therapy program focused on treating metastatic melanoma; ovarian, liver and non-small cell lung cancers; and gioblastoma, which is apparently the most common and aggressive malignant primary brain tumor. Called China Cell Technologies, the joint venture will focus on "immunization against antigens via cells derived from the patient's own blood that are then exposed to the patient's own irradiated cancer cells, and subsequently administered in a series of injections."

According to China Biotech, by targeting cancer stem cells, its treatment is unique. "Other groups target the cancer bulk, or use a generic cancer bulk cell line, or use a generic dendritic cell," the company said. Its approach, however, "purifies the cancer stem cells from the excised tumor, and primes the immune system to recognize and attack those cells. As cancer stem cells are the origin of new tumors, new tumor frequency decreases or is eliminated by this treatment." The company said that Phase 2 clinical trials in the United States, involving 90 melanoma patients given three months to live, kept half of them alive five years after treatment versus a control group with less than a 19-percent survival rate. *See PRLog,* April 9, 2012.

Meanwhile, China Cord Blood Corp. (CCBC) has announced that KKR China Growth Fund L.P. (KKR) will invest $65 million in CCBC "to support its further business expansion and to capitalize on China's fast growing health care services industry." CCBC, which says it is the largest cord blood banking operation in China, evidently has exclusive licenses to service an area with more than 180 million people and more than 1.9 million births annually.

According to the companies, properly stored stem cells in cord blood can be used to treat more than 80 types of diseases, including leukemia, lymphoma, thalassemia and inherited immune system disorders. "CCBC provides an important service to families across China who want to safeguard the lives and health of their newborns," said CCBC Chair and CEO Ting Zheng. According to KKR Member and KKR Great China CEO David Liu, "CCBC runs an impressive operation that meets stringent quality standards and provides a critical medical service to its customers. As we continue to build our China portfolio, we are excited to support a company that is dedicated to improving health care services and making a positive impact on lives in China." *See CCBC/KKR Joint Press Release* and *Bloomberg,* April 12, 2012.

AnaptysBio Partners with Celgene to Develop Novel Antibodies

AnaptysBio Inc., a privately held therapeutic antibody company, has announced a strategic partnership with Celgene Corp. "to develop novel

antibodies against multiple therapeutic targets." Under the agreement, AnaptysBio will use its proprietary SHM-XEL platform to produce therapeutic antibodies to oncology and inflammation-related targets while Celgene gains worldwide rights to develop and market AnaptysBio's discoveries. "In addition to an upfront payment, AnaptysBio is due to receive preclinical and clinical milestone payments from Celgene, as well as royalties upon sales of each product derived from the partnership," according to AnaptysBio.

Company President and CEO Hamza Suria said, "AnaptysBio is uniquely positioned with a state-of-the-art antibody platform and an experienced antibody development team. We look forward to advancing novel antibody therapeutics with Celgene, in parallel with our internal pipeline programs." *See AnaptysBio Press Release*, April 9, 2012.

INVESTOR NEWS

UK Seeks to Revive Biotech Industry with $286-Million Fund

The United Kingdom (U.K.) is reportedly set to launch a $286-million fund operated by the Medical Research Council and Technology Strategy Board aimed at bridging the gap between medical breakthroughs and new drugs and devices. The fund, referred to as the Biomedical Catalyst, is designed to help support small- and medium-sized companies and academics in preclinical or clinical development. "The U.K. boasts a world-leading life sciences sector, which is changing at an incredible pace," Prime Minister David Cameron was quoted as saying. "And I'm absolutely committed to helping it widen its significant foothold in the global market." *See FierceBiotech*, April 11, 2012.

Korea Plans to Increase Investments in Stem Cell Research, Regenerative Medical Treatments

According to a news source, South Korea's Ministry of Health and Welfare plans to invest 33 billion won (approximately US$29 million) in research that can verify stem cell treatment effectiveness and safety. The government funds will also be used to "facilitate the development of global markets" to treat chronic ailments such as arthritis, musculoskeletal disorders, diabetes, and cardiovascular and cerebrovascular diseases.

Previous stem cell studies have focused on basic research, but the Korean government, by increasing its 2012 investment four times above the previous year for practical research and development, hopes to top world rankings in what it calls the "promising field" of regenerative medical treatment techniques. "Through active investment in the research of stem cell and regenerative treatment, we will blaze a trail on rare and hard-to-cure diseases

and build a foundation to industrialize the field into a high-value growth engine," a ministry official reportedly said. *See Korea Times,* April 12, 2012.

Life-Science Investment Affiliate Closes $268-Million Fund

Miami-based H.I.G. Capital, LLC, has announced the closing of H.I.G. BioVentures II with total aggregate commitments of $268 million. Exceeding its $250-million target aimed at investing in health care companies such as pharmaceuticals, medical devices and diagnostics, H.I.G. BioVentures said the funds were raised entirely from limited partners representing "public and pension funds, foundations, funds of funds, and large private family wealth managers."

"We are very pleased with this fund, which we believe is the appropriate size to execute our strategy," said Managing Director Aaron Davidson. "We are seeing more and higher quality deal flow in the health care sector today than at any time in our history. The most effective way to meet the demands of today's evolving and challenging health care market is through innovative products that provide significant patient benefit on a cost-effective basis." *See H.I.G. BioVentures Press Release,* April 10, 2012.

PROLOR Biotech to Raise $75 Million for Clinical Trials on Growth Hormones

In an April 6, 2012, filing with the U.S. Securities and Exchange Commission, Israel-based PROLOR Biotech, Inc. has registered the sale of common stock on the American Stock Exchange in an amount not to exceed $75 million. The cash will be used to finance clinical trials for its long-lasting human growth hormones. According to a news source, the company has $13 million in cash, but lost $15 million in 2011, double the amount from 2010.

In 2011, the company's human growth hormone evidently underwent a Phase II clinical trial involving adults, at a cost of $11.9 million. Based on positive results, PROLOR reportedly plans a Phase III clinical trial this year, along with a Phase II pediatric clinical trial. The company also apparently has hemophilia and obesity treatments in its pipeline. *See Globes [Online]-Israel Business News,* April 8, 2012.

Cerecor Raises $22 Million to Develop Drugs Affecting Human Nervous System

Cerecor Inc., a biopharmaceutical startup focused on "the discovery, development and commercialization of prescription pharmaceuticals whose primary activity is in the human nervous system," has reportedly raised more than $22 million in an "overallotment" of its January 2012 Series A preferred stock financing. According to the Baltimore-based company, the offering "significantly exceeded" the offering maximum of $15 million and came from accredited investors such as its board of directors.

"The completion of this financing is an important step in bringing our lead product, FP01 for the treatment of chronic and acute cough, to the market and to support our early preclinical efforts in cognition and schizophrenia," said company Co-Founder and CEO Blake Paterson. "We are delighted by the enthusiastic response to our offering, as it confirms the quality of our company, its product pipeline and our founding team." *See Cerecor Press Release,* April 4, 2012.

New Investment Initiatives Helping to Finance Biotech Developments

Public, private and non-profit sectors are reportedly changing the way biotechnology companies secure the financing they need to develop drugs. In recent weeks, new biotech financing initiatives have illustrated the trend, with significant investments coming from collaborations among a large pharmaceutical company, traditional biotech investor, foundation, hospital, and two national governments. Burrill & Co. discusses the trend in its 26th annual report on the life sciences industry, "Biotech 2012: Innovating in the New Austerity."

Noting that while life sciences attracted solid financing at the start of the year, such activity has slowed in March, according to Burrill, with "M&A, partnering, and initial public offering activity . . . lackluster." Biotech financing faces hurdles given failures to provide an adequate return on investment. Still, new initiatives, including a partnership between Russia's Rusnano and U.S. venture capital firm Domain Associates, as well as a non-profit entity established by Cleveland's University Hospital to fund and advise physician-scientists on translational research and a related for-profit accelerator, "reflect broad attempts to forge creative new models" to help spur the development of "important new therapies," said Burrill CEO G. Steven Burrill.

Xconomy National Biotech Editor Luke Timmerman addresses the trend in a recent article and explores the collaboration between a disease foundation that used money generated by its investment in a drug a decade ago to fund new drug research and development. Timmerman explains how ethical questions could hinder for-profit and non-profit collaborations, but contends that "the minefield can be navigated if people are thoughtful about it." Because government agencies, foundations and pharmaceutical companies have overlapping missions, Timmerman believes that society will benefit in the long run from broader biotech financing networks. *See Burrill & Co. Press Release,* April 2, 2012; *Xconomy*, April 9, 2012.

BUSINESS CLIMATE

Diversified Approach Seen in Biosimilars Development

With global sales of biosimilars expected to reach US$2.6 billion by 2015 and growing pressures to lower health care costs particularly in less developed countries, major biotech innovator companies are reportedly considering using their biomanufacturing expertise, marketing savvy, infrastructure, and other competitive strengths to enter the biosimilars market in their own right or strike collaborative deals with generics companies to develop biosimilar products. With development costs ranging from $100 million to $200 million to prove to regulators that a biosimilar is enough like the reference product for approval, biotech originators have the resources to effectively compete. Biocon of Bangalore was reportedly one of the first to attempt this in Europe. But while a deal to develop an insulin biosimilar was terminated prematurely, Biocon Founder and President Kiran Mazumdar-Shaw reportedly indicated recently that the company "remains committed to delivering its biosimilar insulins portfolio to global markets," by pursuing "a commercial strategy on its own and through new alliances in other markets."

According to one industry observer, "a diversified competitive arena" is emerging in the biosimilars sector with participants including big pharmaceutical companies, biotechs, contract research organizations, generics and biologics manufacturers, as well as electronics companies. Also apparently fueling an interest among biodrug innovators to get involved in the biosimilar market is a perception that the Food and Drug Administration's recently released guidance on approving these products is "better for innovator drugs, worse for biosimilars." *See Nature Biotechnology*, April 2012.

U.S. Leads Global Nanotech Market

A new research report indicates that the United States and Europe continue to lead the world in major geographic markets for the nantotechnology industry. In its "Nanotechnology Market Forecast to 2014," industry intelligence company RNCOS explores the technology's applications in the biomedical, cosmetic, electronics, energy, and defense industries and forecasts its uses in the future. According to RNCOS, significant growth in the nanotechnology market is expected to reach US$26 billion by the end of 2014. *See SBWire.com*, April 4, 2012.

Biotech Venture Rounds Increase Funding 34% in First Quarter of 2012

According to a *BioWorld Today* columnist, U.S. biotech venture rounds in the first quarter of 2012 with $391 million raised have increased 34 percent over the same period in 2011. Investors reportedly placed more of their money into clinical-stage funds and less in specialty pharmaceutical deals. While the initial

public offering (IPO) market remains "sluggish," the four IPOs this year have raised $265 million with 79 percent going to companies with ongoing clinical trials. Support for early-stage innovators is viewed as a positive development for the biotech industry. *See BioWorld Today*, April 4, 2012.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Presidential Bioethics Panel to Examine Genome Privacy

The Presidential Commission for the Study of Bioethical Issues is seeking public comments "on the ethical issues raised by the ready availability of large-scale human genome sequence data, with regard to privacy and data access and the balancing of individual and societal interests." The commission, which plans to spend the next six months soliciting input from scientific, ethics and health-care patient groups, requests comments by May 25, 2012.

"As a result of the tremendous technological advances that have dramatically reduced the cost of sequencing, the science is at a point where relatively inexpensive, rapid sequencing of whole human genomes appears not only likely, but imminent," the commission noted. "This prospect raises many questions for the scientific, medical, ethics, and patient communities related to how this information can and ought be collected, used, and governed." The commission is particularly interested in protecting the privacy of research subjects, patients and their families. *See Federal Register,* March 27, 2012.

LITIGATION

D.C. Court Relies on *Prometheus* to Find Therapeutic Selection Patents Invalid

Less than two weeks after the U.S. Supreme Court issued *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* ruling that methods for determining an optimal drug dosage to treat certain autoimmune diseases were not patent eligible, a federal court in the District of Columbia similarly found that claims for "Systems, Methods and Computer Program Products for Guiding the Selection of Therapeutic Treatment Regimens" are patent-ineligible. *SmartGene, Inc. v. Advanced Biological Labs., SA*, No. 1:08-cv-00642-BAH (U.S. Dist. Ct., D.D.C., decided March 30, 2012). So ruling, the court granted the plaintiff's motion for partial summary judgment and dismissed the remaining claims and counterclaims.

At issue were patents for "an interactive, computerized program for guiding the selection of therapeutic treatment regimens for a patient based on input provided by a physician." The parties' dispute began with the patent holder, a Luxembourg-based company, filing an infringement action in a Texas federal court which dismissed the matter for lack of personal jurisdic-

tion. Thereafter, the alleged infringer filed this action seeking a declaratory judgment of non-infringement, patent invalidity and patent unenforceability. These proceedings were stayed while the U.S. Patent and Trademark Office (USPTO) conducted concurrent patent validity reexaminations and ultimately concluded that the patents-in-dispute were patentable.

Because the reexamination proceeding did not include consideration of whether the claims were patent eligible under 35 U.S.C. § 101, and, indeed, USPTO cannot review subject matter eligibility during a reexamination proceeding, the court did not defer to USPTO's conclusion. Exploring U.S. Supreme Court decisions, including *Prometheus,* that addressed patents "directed to abstract ideas and mental processes," the court agreed with the alleged infringer that the patents-in-dispute are "directed to nothing more than a mental process in which a person, *e.g.*, a physician, engages when determining a treatment for a patient suffering from a disease or a medical condition." The court also concluded that the patents were invalid under the machine-or-transformation test. According to the court, that the method could speed up a decisionmaking process was insufficient to make what was simply an abstract mental process patent eligible.

NEWS BYTES

The U.S. Patent and Trademark Office (USPTO) **announces** plans to survey patent agents, attorneys and others from large domestic corporations, small- and medium-sized businesses, and universities and non-profit research organizations as part of its efforts to "identify any disjoints between customer expectations and USPTO performance." Comments on the Patents External Quality Survey's utility, time and cost burdens, potential improvements, and ways to minimize response burdens are requested by June 8, 2012.

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service requests **comments** on draft guidelines developed by the International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products. Comments on the draft document, "Testing for Detection of Mycoplasma Contamination," are requested by June 12, 2012.

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Government Enforcement & Compliance Partner **Carol Poindexter** will serve as moderator of a panel discussion during AdvaMed's "**2012 International Medical Device Industry Compliance Conference**," scheduled for May 9-11, 2012, in Stockholm, Sweden. Poindexter's panel involves product distributors who will be discussing the latest compliance issues. Shook, Hardy & Bacon is a conference co-sponsor.

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Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Practice Partners Scott Sayler and David Brooks will participate in DRI's Drug and Medical Device Seminar slated for May 10-11, 2012, in New Orleans, Louisiana. Co-sponsored by SHB, the event will feature "trial skills demonstrations, panel discussions of judges overseeing coordinated pharmaceutical proceedings, and litigation insights from leading defenders of drug and device cases." Brooks will present a session titled "When a Good Medical Device Fails: Successfully Defending Medical Device Suits When Causation Is Not in Doubt," which will address the substantive and strategic consideration of defending these cases. Sayler will also deliver remarks as chair of DRI's Drug and Medical Device Committee.

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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Shook, Hardy & Bacon attorneys are experienced at assisting biotech and life sciences clients with a variety of legal matters such as U.S. and foreign patent procurement; licensing and technology transfer; venture capital and private financing arrangements; joint venture agreements; patent portfolio management; biomedical research and development; risk assessment and management; records and information management issues and regulations; and employment matters, including confidentiality and non-compete agreements. The firm also counsels industry participants on compliance issues, ranging from recalls and antitrust matters to facility inspections, subject to FDA, SEC, FTC, and USDA regulation.

SHB is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most challenging national and international product liability and mass tort litigations.