Shook, Hardy & Bacon L.L.P.

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SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

LAW FIRM NEWS

McDonough Comments on Noteworthy 2012 SCOTUS IP Opinion

Shook, Hardy & Bacon Life Sciences & Biotechnology Partner Madeleine McDonough recently provided expert commentary in "The Catalysts," an *InsideCounsel* magazine article discussing six noteworthy cases and litigation developments that, in the author's opinion, "have spurred change within the corporate realm and introduced new challenges to in-house lawyers."

McDonough addressed the effects of *Mayo Collaborative Services v. Prometheus Laboratories*, a 2012 U.S. Supreme Court decision that invalidated patents for a medical diagnostic test on the ground that they claimed laws of nature. "It's a cautionary tale to companies that are seeking IP protection to review the factors that the Supreme Court set forth in *Mayo* to ensure that they really qualify for an appropriate patent," McDonough said.

IP NEWS

USPTO Issues Memo Interpreting *Mayo v. Prometheus Labs* for Patent Examiners

The U.S. Patent and Trademark Office (USPTO) has issued a memorandum to its patent examining corps to communicate the agency's 2012 interim procedure for a subject-matter eligibility-analysis of process claims involving laws of nature, in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012).

Simply stated, the new guidance provides that "process claims having a natural principle as a limiting element or step should be evaluated by determining whether the claim includes additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself. If the claim as a whole satisfies this inquiry, the claim is directed to patent-eligible subject matter. If the claim as a whole does not satisfy this inquiry, it should be rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter."

The new interim procedure took effect July 2, 2012, and supersedes a March 21, 2012, memorandum issued the day after the U.S. Supreme Court decided that patent claims for a diagnostic procedure involving "administering," "determining" and "wherein" steps failed to transform un-patentable natural laws into patent-eligible applications of those laws. In the Court's words, "the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately."

USPTO will issue comprehensive updated guidance after the Federal Circuit Court of Appeals has had an opportunity to rehear cases pending when *Mayo v. Prometheus Labs* was decided. Among the cases from which USPTO expects to learn more about the patentability of process claims involving laws of nature are *Association for Molecular Pathology v. Myriad Genetics* and *WildTangent v. Ultramercial*.

Four New Regional USPTO Offices Planned

Acting U.S. Commerce Secretary Rebecca Blank has announced that regional U.S. Patent and Trademark Offices (USPTO) will be opened in or near Dallas, Texas; Denver, Colorado; and Silicon Valley, California. They will join an office scheduled to open July 13, 2012, in Detroit, Michigan. According to Blank, "These new offices are an historic step toward further advancing our world's best IP system, and reinforcing the United States as the number one destination for innovation capital, and research and development around the world."

USPTO Director David Kappos said, "By expanding our operation outside of the Washington metropolitan area for the first time in our agency's 200-plus year history, we are taking unprecedented steps to recruit a diverse range of talented technical experts, creating new opportunities across the American workforce." The Detroit office will eventually employ 120 individuals who will help reduce the backlog of patent applications and appeals. No dates have been set for the other office openings. *See USPTO Press Release*, July 2, 2012.

NEW BIO BUSINESS VENTURES

Chinese Companies Agree to Manufacture and Commercialize Antibiotic

TaiGen Biotechnology Co., Ltd. and Zhejiang Medicine Co., Ltd. have reportedly signed a 20-year agreement for the manufacture and commercialization of nemonoxacin, a novel broad-spectrum antibiotic for use in the treatment of respiratory infections. TaiGen will apparently complete the Phase 3 clinical trial in China and will retain full development and commercialization rights in

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Taiwan, the United States, European Union, and Japan. Zhejiang, which will provide an upfront US$8 million payment, additional milestones and royalties to TaiGen, will manufacture, sell and market the product in China through a subsidiary.

Zhejiang Chair Li Chun Bo reportedly said, "We are impressed with nemonoxacin's broad spectrum activity towards drug-resistant bacteria, in particular, MRSA, and excellent safety profile. We are excited to establish this partnership with TaiGen because of its reputation as a premier research-based biotech company in Asia." TaiGen President and CEO Ming-Chu Hsu said, "With nemonoxacin, TaiGen and [Zhejiang] together will bring new medicine to treat unmet medical needs in China. This partnership will not only set a new record for pharmaceutical licensing involving a Taiwanese and a mainland Chinese company but hopefully will also become a model [for] future collaborations." *See PRNewswire-Asia*, June 25, 2012.

INVESTOR NEWS

ScinoPharm Invests $37.6 Million in Cancer Drug Component Manufacturing Facility

Contract manufacturer ScinoPharm Taiwan Ltd. is reportedly building a $37.6-million plant in Tainan that will produce high-potency cytotoxic compounds for use in injectable cancer drugs. Scheduled for completion in 2014, the facility will have space for research and development, quality control, washing, sterilization, manufacturing, filling, lyophilization, packaging, and storage. According to President and CEO Jo Shen, "The global demand for oncological injectable production capacity far exceeds the supply. Many international generic customers of ours have been eagerly searching for partners who can provide a high quality and stable supply of oncological injectable drug products not to mention meet [good manufacturing practice] requirements. We are excited to be able to fill this critical requirement." *See PR Newswire*, June 29, 2012.

Biopharmaceutical Seeks $69 Million in IPO to Develop Immunotherapies

Colorado-based GlobeImmune, Inc. has reportedly filed a registration statement with the U.S. Securities and Exchange Commission indicating its intent to raise up to $69 million in an initial public offering (IPO). The company apparently plans to use the funds to prepare its manufacturing facility and process for commercial-scale production and to further clinical trials for a pipeline of immunotherapies based on its Tarmogens platform, which activates the immune system by stimulating cellular immunity. GlobeImmune is testing cancer product candidates and a hepatitis B treatment. *See GlobeImmune, Inc. Press Release*, July 2, 2012; *FierceVaccines*, July 5, 2012.

Biotech Nets $32.3 Million in Sale of Common Stock for CNS Treatments

According to news sources, a biopharmaceutical company focusing on treatments for inflammation, coagulopathies and disorders of the central nervous system (CNS) has netted $32.3 million from its recent public offering of common stock. Seattle-based Omeros Corp. said it would use the funds "for general corporate purposes, including expenses related to the clinical development of Omeros' two ongoing Phase 3 clinical development programs—OMS302 for use during intraocular lens replacement procedures and OMS103HP for use during arthroscopic partial meniscectomy surgery." *See Omeros Corp. Press Release*, July 2, 2012; *Puget Sound Business Journal*, July 3, 2012.

BUSINESS CLIMATE

Global Pharma Sales Climb to $880 Billion in 2011

According to data compiled by Thomson Reuters, global pharmaceutical sales increased to an "all-time high" of some $880 billion in 2011. The *2011 Pharmaceutical R&D Factbook* also apparently showed, however, that the rate of growth is declining due to a wave of drugs coming off patent and an expanding generics market. Other trends reported include benefits to cancer treatment from advances in personalized medicine, a notable increase in Phase 3 project success rates and improvements to new molecular entity output. Drug companies are reportedly reducing research and development budgets but re-allocating resources to external projects. Overall, the data purportedly leave analysts optimistic about the industry, which appears to be focusing on quality over quantity. *See Reuters* and *Thomson Reuters Press Release*, June 26, 2012.

Employment Growth Documented in Bioscience Industry Development Report

A new **report** prepared by Battelle and the Biotechnology Industry Organization indicates that the bioscience industry "stands out in job growth," and has been a job-creation leader between 2001 and 2010. The report attributes the industry's strength to diversity and innovation, noting that the bioscience market spans "biomedical drugs; diagnostics and devices; agricultural products from animal health to seeds and crop protection; bio-based industrial products such as enzymes for industry chemical processes and bio-remediation, bio-fuels, and bio-plastics."

Despite the economic recession, the U.S. bioscience industry apparently grew by 6.4 percent during the period studied, adding in excess of 96,000 jobs, in comparison to total employment for all private sector industries, where employment fell by 2.9 percent, or a loss of more than 3 million jobs. During the recession, 2007-2010, biotech job losses were just 1.4 percent, compared

with 6.9 percent in the total private sector. The report also finds that bioscience jobs provide higher wages, averaging $82,697 annually in 2010, "more than $36,000 or 79 percent greater than the average paid in the overall national private sector."

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FDA User Fee Bill Gains Presidential Signature

After winning overwhelming and swift approval in the House and Senate, the Food and Drug Administration Safety and Innovation Act (S. 3187), which is expected to generate $6 billion over five years from user fees to fund the agency, has been signed into law by President Barack Obama (D). The bill reauthorizes user fees for another five years. Among other matters, the legislation imposes certain deadlines on the Food and Drug Administration (FDA), including one that reduces the time the agency has to respond to a citizen petition seeking to stay a pending generic-drug application and another that sets a limit on the time FDA has to respond to petitions relating to generic-drug approval. Also intended to speed the approval of cheaper generic drugs are requirements that, for the first time, impose user fees on generic-drug makers.

Provisions that were excluded from the measure include supply chain track-and-trace requirements as well as a prohibition on brand-name manufacturers with a risk evaluation and mitigation strategy from denying drug samples to generic-drug manufacturers. Exclusivity periods under the law are extended to new qualified infectious disease products, and programs to study and provide extended exclusivity periods for new drugs for use in pediatric populations have been made permanent. Other provisions address prescription drug shortages, direct FDA to expand its use of foreign clinical data and give the agency additional authority over medical devices. *See The Washington Post*, June 26, 2012; *The Hill*, July 9, 2012.

FDA Approves Proposed Rule to Mark Medical Devices with Unique Identifier

The U.S. Food and Drug Administration (FDA) has proposed a system that would require most medical devices distributed in the United States to carry a unique device identifier (UDI). Comments are requested by November 7, 2012.

Under the proposed system, manufacturers would be required to label medical devices and device packages with a UDI consisting of a model-specific code and a production identifier, with some exceptions. The proposal would provide "for alternative placement of the UDI or . . . an exception for a particular device or type of devices such as devices sold over-the-counter and low risk devices." Information about each device would be submitted to

a public database, "to ensure that the UDI can be used to adequately identify the device through its distribution and use." The database would not include any patient-specific information.

According to FDA, the system would help health-care professionals and others "to rapidly and precisely identify a device and obtain important information concerning the device." FDA claims that the UDI would also help reduce medical errors and allow FDA, the health-care community and industry "to more rapidly review and assess adverse event reports, identify problems relating to a particular device, and thereby allow for more rapid and effective corrective actions." *See FDA News Release*, July 3, 2012; *Federal Register*, July 10, 2012.

Environmental Engineers Complain About Lack of Progress on EU Nanosilver Regulation

A recent commentary in *Nature Nanotechnology* discusses the questions about nanosilver safety put by the European Commission in December 2011 to its Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). According to authors Steffen Foss Hansen and Anders Baun, with the Department of Environmental Engineering, Technical University of Denmark, the answers to these questions are already known, and they predict what can be expected in SCENIHR's report. The commentary concludes that further reviews are not needed.

The authors suggest that while regulators often seek reviews from scientific advisory groups, "it seems that many of these reviews have been commissioned by regulators with a purpose of delaying decisions on regulatory measures that should be implemented." With the report not due until 2013, the article contends that the European Union (EU) regulatory process will be stalled at least until then and notes, "[b]y initiating one review after the other, regulators have created an unfortunate situation of 'paralysis by analysis' because reviews tend to identify additional research needs rather than the options for optimal regulatory practices."

Titled "When enough is enough," the commentary recommends adopting certain principles already outlined in the literature, such as "(1) the development of clear rules defining the ingredients of a product using the unique physical and chemical attributes of the ingredients to track production, use and environmental release/dispersal data; (2) the assessment of what information is needed to oversee safe use of nanosilver; (3) the evaluation of the relevance and shortcomings of current silver-relevant regulations." The authors also note that the precautionary principle has been recommended in at least one country and that a German agency called for producers "not to use nanosilver in foods and everyday products. However, little progress has been made in implementing any of these recommendations."

India May Tighten Drug Marketing Code

According to a news source, India's Department of Pharmaceuticals will meet with industry associations and the Medical Council of India on July 18, 2012, to consider whether more stringent marketing rules should be imposed on drug manufacturers. In 2011, the department apparently introduced voluntary standards to restrict pharmaceutical companies from offering to physicians and suppliers gifts, pecuniary incentives or benefits in kind, including travel, sporting and leisure activities. Due to ongoing complaints about such practices, a government spokesperson reportedly said, "The department has, therefore, decided to review the situation and speak to various industry associations. If required, it may also make the code of conduct mandatory." The 12,000 pharmaceutical companies that sell drugs in India are not permitted to advertise prescription products, thus sales are apparently driven by physicians and chemists. *See Business Standard*, July 8, 2012.

LITIGATION

Affordable Care Act Provisions for Biosimilars Approval Remain Intact

The U.S. Supreme Court largely **upheld** the constitutionality of the health-care reform law known as the Affordable Care Act, thus allowing the Food and Drug Administration (FDA) to move forward with the implementation of provisions creating an approval pathway for biosimilars, generic drugs that are the equivalent of brand-name biologics.

The Biotechnology Industry Organization (BIO) issued a statement following the ruling, indicating that it would "continue to work with relevant federal and state agencies to ensure implementation of the law in a manner that helps enable the U.S. biotech community's continued development of lifesaving cures and other medical breakthroughs while expanding patient access to these critical cures, medicines and innovations." While no manufacturers have yet to submit an application for FDA's approval, it is apparently anticipated that the first biosimilars will enter the U.S. market in 2014 or 2015.

Meanwhile, medical device manufacturers face a new 2.3 percent excise tax under the law. Scheduled to take effect in 2013, this provision was intended to help pay for health-care reform. The tax will affect medical device products diagnosed for human use, but apparently exempts prescription eyeglasses, contact lenses and hearing aids, in addition to over-the-counter devices. Efforts to repeal the tax have, to date, been unavailing. *See BIO News Release* and *Law360*, June 28, 2012; *Healthcare IT News*, June 29, 2012.

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NEWS BYTES

The National Institute for Occupational Safety and Health (NIOSH) publishes "General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories." NIOSH conducts research and makes recommendations for preventing work-related injury, illness and death.

The U.S. Patent and Trademark Office seeks feedback on its First Action Interview Pilot Program, which has been extended while under review. Designed to expedite disposition of an application by enhancing communication between an applicant and an examiner, the program allows patent applicants to "conduct an interview with an examiner prior to the issuance of an Office action, but after receiving the examiner's search results and initially identifying issues." Comments are requested by August 8, 2012.

The Food and Drug Administration seeks public comment on "the statement of work for an assessment of the Program for Enhanced Review Transparency and Communication for New Molecular Identity (NME) New Drug Applications (NDAs) and Original Biologics License Applications (BLAs)." Comments on the program, which would increase communications by increasing interactions between FDA and applicants, are requested by August 6, 2012.

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