Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Mayo v. Prometheus Laboratories Argued Before U.S. Supreme Court

With major industries weighing in as *amici* on the patentability of diagnostic medical tests, the U.S. Supreme Court heard arguments in a significant patent case on December 7, 2011. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, No. 10-1150 (U.S., *cert.* granted June 20, 2011). On a previous remand from the Court, the Federal Circuit Court of Appeals determined that the asserted medical treatment (or method) claims to which Prometheus held an exclusive license were drawn to statutory subject matter and thus, that Mayo infringed those patents by announcing its intent to use in its clinics the technology covered by the patents in suit and to sell its test to other hospitals.

The U.S. Supreme Court was asked to consider "whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve 'transformations' of body chemistry." Mayo argues that if the patents are upheld, Prometheus will have a monopoly on all uses of a natural relationship between the metabolites created by a stomach medicine and its effect on the human body. Thus, according to Mayo, doctors familiar with the patented method could not use it to adjust a patient's proper dosage.

Those supporting Mayo's position, including the American Medical Association, contend, "Patents on scientific observations threaten to stifle innovation, including the development of personalized medicine." Drug and biotechnology companies, however, support patent-holder Prometheus. The Pharmaceutical Research and Manufacturers Association said, "Medical-process patents involving pharmaceuticals . . . are products of human ingenuity, and cannot be found in nature."

Among the questions considered during oral argument were whether (i) the patent preempts the use of a law of nature, (ii) the relationship between the section 101 patentability inquiry and the novelty/non-obviousness standard

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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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used to reject invalid patents has been blurred, and (iii) certain precedents involving the standard for patenting a newly discovered natural law are applicable to the case. *See Bloomberg*, December 6, 2011; *The New York Times* and *PatentlyO.com*, December 8, 2011.

NEW BIO BUSINESS VENTURES

MacroGenics, Servier Sign Agreement to Develop Tumor-Targeting Antibody

MacroGenics Inc., a Maryland-based privately held biotech, and Servier, France's largest privately held pharmaceutical company, have entered into an option for a license agreement to develop and market a tumor-targeting antibody called MGA271. Described as MacroGenics' proprietary monoclonal antibody product candidate, MGA271 "incorporates multiple complementary mechanisms of action including enhanced immuno-stimulatory properties and targeting of tumor vasculature," according to the company.

Under the agreement, MacroGenics retains full development and commercialization rights in Canada, India, Japan, Korea, Mexico, and the United States, while Servier has the option to obtain an exclusive license in all other countries. The agreement includes a $20-million upfront payment to MacroGenics, potential milestone payments that total $60 million and "an additional $390 million in clinical, regulatory and commercialization milestone payments." MacroGenics may also receive royalties on future net sales, with both companies sharing clinical development costs following the option. *See MacroGenics Press Release,* December 1, 2011.

INVESTOR NEWS

Biotech Startup Raises $15 Million to Fund Protein Therapeutics

Allena Pharmaceuticals, a biotech startup formed to develop and market non-systemic oral protein therapies to treat metabolic and orphan diseases with a particular focus on kidney and urologic diseases, has raised $15 million in Series A venture capital financing. Leading the round were Bessemer Venture Partners, Frazier Healthcare and Third Rock Ventures. The Massachusetts-based startup is reportedly developing enzyme-based drugs to take orally, rather than by injection, thereby producing low-level toxicity to target metabolite-related diseases.

"Allena's innovative and proven approach for the development of oral protein therapeutics offers the potential to provide breakthrough treatments for patients with limited or no treatment options," said President and CEO Alexey Margolin. "We are committed to rapidly creating value for our investors and working with renowned scientific leaders in metabolic, nephrologic and

urologic disorders to advance our programs. We expect to announce our initial disease indication shortly." *See Allena Pharmaceuticals Press Release* and *Xconomy,* November 16, 2011.

Exact Sciences Completes Public Offering of Common Stock

Exact Sciences Corp., a molecular diagnostics company focused on colorectal cancer, has announced the completion of a public offering of 3.593 million shares of common stock priced at $8 a share. With net proceeds of approximately $27.1 million, the company said the offering will go toward corporate and working capital, including efforts to obtain Food and Drug Administration approval for its stool-based colorectal cancer screening product and product marketing. *See Exact Sciences Press Releases*, December 6 and 9, 2011.

BUSINESS CLIMATE

University Research Creates New Companies and Generates Patent Applications

An Association of University Technology Managers (AUTM) survey report has found that university research conducted in 2010 led to 651 new companies, an increase of 9.2 percent over 2009, and 12,281 new patent applications, a 46.8 percent increase. Scheduled for release at the end of 2011, the "AUTM U.S. Licensing Activity Survey: FY 2010" is the 20th report issued by the association "to share quantitative information about and real-world examples of licensing activities at U.S. universities, hospitals and research institutions."

Report highlights include (i) $2 billion in total licensing income, a 3-percent increase compared to 2009; (ii) $59 billion in sponsored research expenditures, a 10.5-percent increase; and (iii) 20,642 disclosures, up 1.6 percent. According to other survey data, 657 new commercial products were introduced and 3,657 startups were still operating as of the end of fiscal year 2010. "This year's data reveal that the economic recession has continued to affect universities; however, we are pleased to see that startup creation has remained strong," Shawn Hawkins, AUTM vice president for metrics and surveys, was quoted as saying. *See BNA Life Sciences Law & Industry Report,* December 2, 2011.

Boston Garners Top Life Sciences Cluster Spots in Global Report

Boston has ranked first in five of six cluster categories related to the life sciences sector, according to a new global report from Jones Lang LaSalle, a real estate services firm. According to the report, the "Greater Boston area is a leading global industry cluster that supports all aspects of the life sciences industry including biotechnology, pharmaceuticals, medical devices, diagnostics and bioinformatics." It came in second in venture capital funding, trailing San Francisco's Bay Area by nearly $700 million.

The report notes that the Boston area features more than 85,000 high-tech research and development (R&D) employees and more than 340,000 hospital and medical employees with job growth that continues to increase and outpace other life sciences clusters. The area also apparently has "seven times the number of workers in biotech R&D than the national average." In addition, Massachusetts reportedly receives some 13 percent of all National Institutes of Health funding and has trailed only California (the location of three of the country's largest life sciences cluster regions) as a recipient. *See Mass High Tech*, November 29, 2011.

Cuba, China Agree to Strengthen Biotechnology Collaboration

Cuba and China have reportedly signed agreements to deepen their collaboration on biotechnology. Speaking at the recent "6th Joint Work Meeting for Biotechnology Cooperation," Cuban Science Minister Jose Miyar Barrueco evidently asserted that favorable conditions continue to exist for such cooperation.

According to the Cuban state-run National News Agency, the deal seeks to strengthen the two countries' ties in biomedicine and bioagriculture for 2012-2016, and create ways to strengthen bilateral exchanges in agriculture, health, regulatory policy, industrialization, and research and development. Both countries reportedly want to consolidate the achievements of their joint ventures and develop joint research centers. *See The Pharma Letter,* November 28, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

User-Fee Program for Biosimilar Biological Products on FDA Meeting Agenda

The Food and Drug Administration (FDA) has **scheduled** a December 16, 2011, public meeting "to discuss the proposed recommendations for a user fee program for biosimilar products for fiscal years (FYs) 2013 through 2017." The agency requests electronic or written comments by January 6, 2012. According to a news source, the pharmaceutical industry praised FDA for seeking stakeholder input; it apparently supports a regulatory program funded with both tax dollars and user fees.

FDA's proposal would include four types of fees: biosimilar-product-development, marketing-application, establishment, and product fees. According to its *Federal Register* notice, the establishment and product fees would likely equal similar fees imposed under the Prescription Drug User Fee Act. The revenue generated by the user fees would fund, among other things, product development meetings; investigational new drug applications; the scientific, regulatory and policy infrastructure required for the review of biosimilar

biological product applications; and the development of standards for products subject to review and evaluation. *See Law360*, December 6, 2011; *Federal Register*, December 7, 2011.

Meanwhile, a recent *Scientific American* article explained why biosimilar products are unlikely to provide the same cost savings as generic drugs, which can usually be approved without costly animal and human trials to assess safety and efficacy. Apparently, the tools to compare the complex features of drugs harvested from cultures of living cells have not yet been fully developed, tremendous variations in drug molecules are a part of the biosimilar drug manufacturing process, and human reactions to biological drugs are difficult to predict.

One company lab director has suggested that few experts believe that biosimilars will be approved without running clinical trials. Still, FDA guidelines for the approval of biosimilars are expected by the end of 2011, and agency officials predict that cost savings of 10 to 30 percent, or up to $300 billion by 2029, could be realized with the introduction of generic biological drugs to the market. *See Scientific American*, December 5, 2011.

FDA Issues Draft Guidance on Pharmaceutical Co-Crystals

The Food and Drug Administration (FDA) has **announced** the availability of industry draft guidance titled "Regulatory Classification of Co-Crystals." Representing the Center for Drug Evaluation and Research's current thinking on the appropriate classification of co-crystal solid state forms, the **guidance** provides those seeking new drug applications (NDAs) and abbreviated new drug applications (ANDAs) information about "data that should be submitted to support the appropriate classification of a co-crystal and the regulatory implications of the classification."

According to FDA, "co-crystals are solids that are crystalline materials composed of two or more molecules in the same crystal lattice" that have been of "significant interest in drug product development." FDA requests comments on the draft guidance by March 1, 2012. *See Federal Register,* December 2, 2011.

USPTO Issues Final Rule Revising Rules of Appellate Practice

The U.S. Patent and Trademark Office (USPTO) has finalized **amendments** to the rules of practice before the Board of Patent Appeals and Interferences in *ex parte* appeals. The changes will affect all appeals "in which a notice of appeal is filed on or after January 23, 2012." Among other matters, the revisions remove several briefing requirements, give the Board jurisdiction over an appeal earlier in the process, create new procedures for appellants to seek review "of an undesignated new ground of rejection in either an examiner's answer or in a Board decision," and "clarify that, for purposes of the examiner's

answer, any rejection that relies upon Evidence not relied upon in the Office action from which the appeal is taken shall be designated as a new ground of rejection."

The *Federal Register* notice announcing the final rule also indicates that USPTO withdrew a related, previously published final rule that never took effect. *See Federal Register*, November 22, 2011.

European Medicines Agency Seeks Feedback on Biosimilars Guideline

The European Medicines Agency has issued for public comment a "**Concept paper on the revision of the guideline on similar biological medicinal product**." The document recommends several revisions to the 2005 guideline on biosimilar medicinal products; comments are requested by February 29, 2012.

According to the concept paper, experience has shown that numerous designations are used for "biosimilar" products, and the term is often used in an inappropriate way. Thus, "[i]t may therefore be prudent to discuss if a definition of 'biosimilar,' in extension of what is in the legislation and relevant CHMP [Committee for Medicinal Products for Human Use] guidance, is necessary."

Other issues under consideration include revisions that would address (i) "[a] discussion of equivalence of efficacy and safety aspects," (ii) whether the same "pharmaceutical form, strength and route of administration" is possible for a biosimilar and a reference medicinal product, and (iii) the utility of the current guidelines list of references, some of which are outdated.

LITIGATION

Minnesota Supreme Court Examines Intersection of Blood Sampling and Genetic Privacy Laws

The Minnesota Supreme Court has determined that a state statute authorizing the Department of Health to collect newborn blood samples is limited and that certain alleged uses made of the blood samples may have violated the state's Genetic Privacy Act. ***Bearder v. Minnesota*, No. A10-0101 (Minn., decided November 16, 2011)**.

The lawsuit was filed by nine families with 25 children born between 1998 and 2008. The children's blood was sampled and tested for heritable and congenital disorders under the state's newborn screening program. The plaintiffs alleged that the Genetic Privacy Act required written parental consent before the Department of Health could store the specimens collected or authorize public-health research to be conducted on the samples. The court noted that hundreds of thousands of specimens were still in storage and that additional third-party research had apparently been conducted using the samples.

In a split ruling, the court held that the privacy law's definition of "genetic information" includes blood samples and that the Department of Health is exempt from its provisions only to the extent authorized by law. Thus, while "[t]he newborn screening statutes . . . expressly authorize the Commissioner to use the blood samples without written informed consent only to the extent necessary to conduct tests for heritable and congenital disorders and conduct follow-up services," this authority is not "unlimited." Accordingly, the court ruled that use of "genetic information for purposes other than the screening of newborn children and for follow-up services requires written informed consent."

The Genetic Privacy Act was adopted in 2006, according to the court, and applies to genetic information collected on or after August 1 of that year. Because the lower court concluded that the Department of Health had not violated the privacy act, it did not consider whether "any parties had established the facts necessary to show that their children's blood samples had been used, stored, or disseminated in violation of the Act." The court remanded the case for further development of the record.

EU Court of Justice Interprets Law Extending Patent Protection for Medicinal Products

The Court of Justice of the European Union (ECJ) has issued two rulings interpreting EU law at the request of British courts addressing whether drug makers can obtain a supplementary protection certificate (SPC), which extends patent protection, for products with active ingredients additional to those specified in the original patent. ***Medveda BV v. Comptroller Gen. of Patens, Designs and Trade Marks*, 2011 E.C.J. C-322/10 (decided November 24, 2011)**; ***Georgetown Univ. v. Comptroller Gen. of Patents, Designs and Trade Marks*, 2011 E.C.J. C-422/10 (decided November 24, 2011)**.

The issues arose in cases involving patents for pertussis and papillomavirus vaccines that are effective against multiple diseases with the addition of other active ingredients.

According to ECJ, as long as all other requirements are met under Article 3(b) of Regulation No. 469/2009, the competent industrial property authority of a member state may grant "a supplementary protection certificate for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the application for a special protection certificate contains not only that combination of the two active ingredients but also other active ingredients." While pharmaceutical interests reportedly reacted favorably to the ruling, some reservations were expressed about that part of the court's rulings limiting companies to one SPC per patent. *See BNA Life Sciences Law & Industry Report*, December 2, 2011.

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NEWS BYTES

A National Institutes of Health (NIH) electronic catalogue of unpatented research materials is now available online. Intended to streamline technology transfer, the resource will allow companies to find and license unpatented materials with a ready-to-go contract and pay online to receive lab materials quickly, and will provide "faster turnaround time and simplify the process for companies to find research materials available from NIH labs."

The National Institutes of Health publishes a list of U.S. government patents relating to a method to elicit immune responses to specific cancers and AIDS and available for licensing in the United States.

The Food and Drug Administration schedules a December 19, 2011, public meeting and seeks comments on developing legislation authorizing the agency to collect fees for the review of human generic drug applications and associated inspections. Comments are requested by January 6, 2012.

The U.S. Patent and Trademark Office requests comments by January 30, 2012, on locations for two additional satellite offices that would "better connect patent filers and innovators with the offices, enhance patent examiner retention, and improve recruitment of patent examiners."

The U.S. Patent and Trademark Office launches patent prosecution highway pilot programs with China and Iceland. Effective for an extendable one-year period ending November 30, 2012, the programs will allow patent offices in the respective countries to benefit from work previously done in the other office, thus reducing examination workload and improving patent quality.

OFFICE LOCATIONS

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