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ISSUE 5 | JANUARY 13, 2011

BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

China Sets Ambitious Innovation and Patent Goals

China's State Intellectual Property Office recently issued a strategy document outlining its IP goals for the next 10 years. According to the document, China will focus in the near term on improving its patent laws and regulations and has set a goal of two million patent filings by 2015. The country also plans to double the number of patent examiners to 9,000 by then, which would outpace the 6,300 currently working in the United States. China will also apparently seek to double the number of patents its residents file abroad and will strengthen patent enforcement mechanisms. U.S. Patent and Trademark Office Director David Kappos reportedly referred to China's 2015 targets as "mind-blowing numbers." He also commented, "The leadership in China knows that innovation is its future, the key to higher living standards and long-term growth. They are doing everything they can to drive innovation, and China's patent strategy is part of that broader plan." *See The New York Times*, January 1, 2011.

NEW BIO BUSINESS VENTURES

Sinochem Group Announces Joint Venture with Global Life Sciences Company

Sinochem Group, a China-based oil and chemicals company, has announced an agreement with Royal DSM N.V., a Dutch global life sciences and material sciences company, to form a global anti-infective joint venture to be headquartered in Hong Kong. According to a Sinochem press release, the company will pay €210 million ($278.1 million) for a half-stake in the joint venture, which needs approval from Chinese and European Union regulatory authorities.

"This partnership will benefit from the strengths of both Sinochem Group and DSM and will allow us to grasp market opportunities in China and other high growth economies, in addition to securing European and American access to high quality products," said DSM Managing Board Member Stephan Tanda.

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Sinochem Group Vice President Pan Zhengyi said the investment was in line with Chinese central government plans to invest in seven key industries of strategic importance, including four pertaining to biotechnology. He claimed it would allow the company to build its presence in the biochemical industry while saving energy consumption and reducing waste discharge by leveraging biotechnology. *See Sinochem Group Press Release*, December 17, 2010.

INVESTOR NEWS

Large Pharmaceutical Companies Look to Buy Niche Indian Biotech Firms

Major pharmaceutical companies are reportedly buying niche biotech firms in India to take advantage of emerging opportunities involving biosimilar drugs, which are expected to have a market share of approximately $78 billion by 2013. Anticipating a rising worldwide demand for generic versions of patented biotechnology drugs, the companies are apparently partnering with the Indian biotechs to develop and market their biosimilar drugs on a global basis.

"Companies are taking the route of acquisition to diversify their product offerings," Arun Chandavarkar, chief operating officer of India-based Biocon was quoted as saying. "Also, as biotechnology products have a long-gestation period for development, the inorganic route is one of the options before them." Biocon has reportedly entered into an agreement with a global pharmaceutical company to commercialize four biosimilar insulin-segment products: recombinant human insulin, glargine, aspart, and lispro.

A pharmaceutical analyst at PINC Research has cautioned pharmaceutical companies, however, to take care regarding biosimilar drugs. "Unlike traditional drugs, biotech drugs are complex," Sushant Dalmia said. "Hence, it is difficult to establish comparability between generics and innovator drugs. This has posed regulatory hurdles for approval of biosimilar drugs. Once clarity emerges on the regulatory front, especially in the U.S., biosimilar drugs would provide a huge potential for Indian companies, given the high margins and low competition." *See Business Standard,* January 4, 2011.

Avalon Ventures Closes Ninth and Largest Fund

Avalon Ventures, located near San Diego, California, has reportedly closed capital commitments of $200 million for its ninth and largest fund, Avalon Ventures IX, LP. The firm will apparently continue to invest in early-stage, high-tech digital media and life sciences companies primarily along the West Coast and in the Northeast.

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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"Avalon Ventures IX LP was more than 33 percent oversubscribed compared to the original target of $150 million and virtually all institutional investors in the two preceding Avalon funds committed to the ninth fund," according to a statement released by the firm's founding partner, Kevin Kinsella. Avalon has evidently made six investments out of its newest fund, including San Diego-based Sova Pharmaceuticals (sleep-disorder drugs) and RQx Pharmaceuticals (broad-spectrum antibiotics). *See Avalon Ventures Press Release; Xconomy San Diego,* January 10, 2011.

BUSINESS CLIMATE

Report Suggests Europe Could Become Marine Biotech Leader by 2020

The Marine Board of the European Science Foundation has released a report that suggests Europe could become a global leader in marine biotechnology by 2020, particularly by cultivating microalgae for fuel. Calling marine organisms in Europe's four seas and two oceans "a living library of diversity," the foundation states that marine biotechnologists could develop sustainable food and energy, drugs and health treatments, and industrial materials and processes. Microalgae biofuels could reduce Europe's greenhouse gas emissions by 20 percent, according to the foundation.

"Marine biotechnology not only creates jobs and wealth, it can also contribute to the development of greener, smarter economies," said Marine Board Chair Lars Horn in a statement. "Japan, China and the USA are already investing heavily in marine biotechnology. If we fail to act, Europe will lose out."

The report calls for Europe to (i) develop new marine biotechnology research strategies and programs "aligned across the national, regional and pan-European levels," (ii) strengthen collaboration between academic research and industry, (iii) secure "fair and equitable access" to marine genetic resources, and (iv) create a stronger identity and communication to raise awareness of European biotechnology research. *See Marine Board of the European Science Foundation Press Release,* December 14, 2010.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

House Members Clarify Intent of Biosimilars Law

Democratic and Republican House representatives have submitted a letter to the Food and Drug Administration (FDA) to clarify congressional intent in enacting the Biologics Price Competition and Innovation Act. FDA is currently accepting comments on its preliminary efforts to implement the law. Authored by Representatives Anna Eshoo (D-Calif.), Jay Inslee (D-Wash.) and Joe Barton (R-Texas), the December 21, 2010, letter contends that the law

"does not provide 'market exclusivity' for innovator products." One of the questions for which FDA sought comment implied that the agency has interpreted the law as providing marketing exclusivity for biological products.

According to the letter, the law provides "data exclusivity for 12 years from the date of FDA approval. There are significant and critical differences between the two types of exclusivity. Data exclusivity only prohibits the FDA from allowing another manufacturer to rely on the data of an innovator to support approval of another product. Importantly, it does not prohibit or prevent another manufacturer from developing its own data to justify FDA approval of a similar competitive product." The letter also clarifies what Congress considered in relation to "data exclusivity for modifications to an innovator product, known as 'evergreening,'" as well as "next generation" products, that is, those products offering significant changes in safety, purity or potency.

The letter emphasizes that the authors "care deeply about patient access to biologics" as well as "the advancement of science and our ability to treat the most complex diseases. Any proposal to limit the definition of a 'new' product, and thus one which is entitled to its own period of data exclusivity has the potential to stifle innovation and negatively impact patient care. . . . We must encourage companies to further the evolution of life-saving drugs."

Bioethics Commission Calls for Further Development of Synthetic Biology

The Presidential Commission for the Study of Bioethical Issues has issued a **report** that calls for ongoing federal oversight in the emerging field of synthetic biology.

Recognizing the "great potential" of the science devoted to engineering new organisms through manipulated or manufactured DNA, the commission claims that synthetic biology poses few risks in its infancy and offered **18 recommendations** to minimize risks and foster innovation through self-regulation by synthetic biologists.

"We considered an array of approaches to regulation—from allowing unfettered freedom with minimal oversight and another to prohibiting experiments until they can be ruled completely safe beyond a reasonable doubt," said Commission Chair Amy Gutmann in a statement. "We chose a middle course to maximize public benefits while also safeguarding against risks."

President Barack Obama (D) asked the commission of 13 scientists, ethicists and public-policy experts to review the implications of synthetic biology after scientist J. Craig Venter in May 2010 announced that he had produced a duplicated known genome and transplanted it into another bacterial cell that took over the organism. Ethics education for researchers in the field was among the recommendations offered by the commission.

The report drew criticism from more than 50 global environment groups, which signed a **letter** to federal officials urging that commercial use of synthetic organisms be halted until risks are understood and regulations developed because "self regulation" means "no real regulation or oversight." The letter said, "The commission's lack of attention to the ecological harms posed by synthetic biology is irresponsible and dangerous." *See Presidential Commission for the Study of Bioethical Issues Press Release, The New York Times,* December 16, 2010.

IOM Publishes Workshop Summary, Participants Addressed Genomic Discovery and Application Gap

The Institute of Medicine (IOM) has released a **summary** of the workshop held by its Roundtable on Translating Genomic-Based Research for Health in July 2010 at which government, industry, academic, and nonprofit participants discussed obstacles to the translation of genome sequencing discoveries into "clinically relevant drug, diagnostic, or preventive measures." Among other matters, the participants addressed precompetitive collaborations, public-private partnerships, large-scale data networks, and biospecimen quality.

Barbara Mounho, et al., "Global Regulatory Standards for the Approval of Biosimilars," *Food & Drug Law Journal* (2010, Vol. 65, Issue 4)

As the Food and Drug Administration (FDA) continues to develop a regulatory pathway for the approval of biosimilars, regulatory and policy executives with a number of major pharmaceutical companies have co-authored this article to provide the agency with an overview of the regulatory regimes already in place in other countries. They outline the approaches taken by Canada, the European Union, Japan, South Africa, and the World Health Organization, noting how the approaches are similar and how they differ. The authors also suggest that FDA could provide global leadership by addressing questions other countries are trying to answer, such as (i) "Are current pharmacovigilance requirements and practices sufficient to identify promptly which of several multi-sourced biologics is the cause of an adverse event?"; (ii) "What if the adverse event occurs months after exposure to the product?"; and (iii) "How will interchanging one product for another affect the patient's immune response?"

LITIGATION

Federal Circuit Reverses Patent Appeals Board on Obviousness Ruling and Commercial Success Evidence

The Federal Circuit Court of Appeals has determined that the Board of Patent Appeals and Interferences incorrectly rejected on obviousness grounds a patent claim involving physical and air shields to prevent the clogging of a

nozzle to a Wurster coater, which sprays coating material onto pharmaceutical ingredients. ***In re Glatt Air Techniques, Inc.*, 2010-1141 (Fed. Cir., decided January 5, 2011)**. The '503 patent was issued in 1993 and subject to reexamination at the request of a third party in 2007. Claim 5 of the '503 patent was written in Jepson format, "where the preamble recites prior Wurster coaters, and the invention is an improvement, i.e., a shield used in the Wurster coater."

The examiner and appeals board determined that the shielding technology "would have been obvious to one having ordinary skill in the art at the time the invention was made" and that Glatt Air's secondary considerations evidence "of unexpected results, long-felt need, and commercial success due to the improvement" was insufficient to overcome the prima facie case of obviousness. According to the Federal Circuit, the German patent for the Wurster coater taught that an air wall could be used to *remedy* a clogged nozzle, but did not teach a means of shielding the nozzle to *prevent* clogs. In that respect, Glatt Air's invention, which prevents circulating particles from prematurely entering the initial spray pattern either by an air wall or a cylindrical partition and thus stops clogs altogether, was not obvious.

The court also determined that the board erred in requiring commercial-success evidence as to both methods of preventing clogs (the air wall and the physical wall), finding this position inconsistent with its precedent. The court said in this regard, "It seems unlikely that a company would sell a product containing multiple, redundant embodiments of a patented invention. The fact that Glatt's commercial products only contain one type of shielding means does not make its commercial success evidence irrelevant."

Medical Treatment Claims Deemed Patentable on Reconsideration After *Bilski*

The Federal Circuit Court of Appeals has confirmed its earlier decision, rendered before *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), was decided, and ruled that methods for determining the optimal dosage of thiopurine drugs used to treat gastrointestinal and non-gastrointestinal autoimmune diseases recite patentable subject matter under § 101. ***Prometheus Labs. Inc. v. Mayo Collaborative Servs.*, 2008-1403 (Fed. Cir., decided December 17, 2010)**. The court initially upheld the patent claims under the machine-or-transformation test, finding that "the 'administering' and 'determining' steps were transformative and not merely data-gathering steps under the second prong of the test."

According to the Federal Circuit, *Bilski* rejected "the machine-or-transformation test as the sole, definitive test for determining patent eligibility of a process under § 101. . . . Instead, the Court declined to adopt any categorical rules outside the well-established exceptions for laws of nature, physical phenomena, and abstract ideas." The U.S. Supreme Court did not reject the machine-or-transformation test outright, instead characterizing it as "a useful and important clue, an investigative tool, for determining whether some

claimed inventions are processes." The Court vacated the Federal Circuit's ruling upholding the Prometheus Laboratories patent, and remanded for consideration in light of *Bilski*.

On remand, Prometheus argued that "its asserted claims involve a particular transformation of a patient's body and bodily sample and use particular machines to determine metabolite concentrations in a bodily sample," thus taking its claims beyond abstraction and involving "an application of a law of nature, not the law itself." The Mayo Clinic, which sought to use its own metabolite measuring tests, argued that the claims "are invalid because they preempt all practical use of naturally occurring correlations between metabolite levels and drug efficacy."

The court determined that (i) "the method claims recite a patent-eligible application of naturally occurring correlations between metabolite levels and efficacy or toxicity, and thus do not wholly preempt all uses of the recited correlations"; and (ii) "the treatment methods claimed in Prometheus's patents in suit satisfy the transformation prong of the machine-or-transformation test. . . . The transformation is of the human body and of its components following the administration of a specific class of drugs and the various chemical and physical changes of the drugs' metabolites that enable their concentrations to be determined."

NEWS BYTES

The U.S. Patent & Trademark Office establishes online **subscription center** for public access to office newsletters and alerts.

The National Institute for Occupational Safety and Health **requests comments** on its draft "Current Intelligence Bulletin" regarding occupational exposure to carbon nanotubes and nanofibers. The draft calls for minimizing workplace exposures and proposes a recommended exposure limit. A public meeting to address stakeholder comments will be held February 3, 2011, in Cincinnati, Ohio, and comments are requested no later than February 18.

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Pharmaceutical and Medical Device Litigation Partner **Lori McGroder** will participate as a panelist in a Berkley Life Sciences LLC Risk Management Webinar on January 26, 2011, at 2:00 p.m. (EST). Titled "Inoculating Clinical Trials from Litigation Risks," the program will "offer tips to help life science firms build immunity to the risks that can lurk in the clinical trial process." Among the topics to be addressed are the potential liabilities presented by "an investigator's perceived lack of independence," "common criticisms of company-sponsored trials," and "the best legal and risk strategies to avert clinical trial litigation." Online **registration** is available.

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Shook, Hardy & Bacon Intellectual Property Of Counsel Tom Moga will discuss the relationship between genetic resource recording and the World Trade Organization's TRIPS Agreement at the American Intellectual Property Law Association's 2011 Mid-Winter Institute. Slated for February 2-5, 2011, in Orlando, Florida, the institute will feature Moga as part of its session "on the state of Section 101 eight months post-*Bilski*, including how courts are approaching subject matter patentability in both the computer/electronics and biotech industries," as well as its impact on international treaties.

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