Shook, Hardy & Bacon L.L.P.

ISSUE 8 | FEBRUARY 24, 2011

BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

WIPO Announces Increase in Filings Under International Patent Treaty

The World Intellectual Property Organization (WIPO) has released data on international patent filings under the Patent Cooperation Treaty showing a nearly 5 percent increase from 2009 to 2010. China saw the strongest growth in filings at more than 56 percent, and patents related to digital communication technology led other fields with a 17.3 percent increase. Biotechnology patent filings decreased 1.5 percent, while micro-structural and nanotechnology patent filings fell by 2.3 percent. *See WIPO News & Events*, February 9, 2011.

Senate Judiciary Committee Holds Hearing to Tackle Online IP Infringement

The Senate Judiciary Committee recently held a hearing to discuss online infringement and online sales of counterfeit goods. Apparently a growing problem, online piracy could potentially pose health risks to consumers who buy prescription drugs from what appear to be legitimate Websites.

Led by Senator Patrick Leahy (D-Vt.), the hearing followed the committee's 2010 unanimous vote to approve the Combating Online Infringement and Counterfeits Act, which would have bolstered law enforcement's authority to suspend infringers from profiting from intellectual property theft. Indicating that he plans to introduce similar legislation in the 112th Congress "before rogue Websites harm more businesses," Leahy called the problem of online infringement "real" and "substantial." "If you have someone breaking into a warehouse and stealing a few hundred thousand dollars worth of items, you'd want to get after that," he told a news source. "You have these people stealing millions and billions of dollars … inaction is not an option."

Those testifying at the hearing included representatives from Rosetta Stone Inc., The Authors Guild of America, The Go Daddy Group Inc., Verizon Communications Inc., and Visa Inc. "I don't think we can really make progress on this until we have cooperation from what we call all of the 'big five' players," said Go Daddy's Christine Jones. "That would be domain name registrars, hosting service providers, payment card processors, Internet service providers, and online advertising providers. Without proper effort from all of these players, the

criminals that Go Daddy works hard to take offline every day will come back almost certainly as customers of one of our more lax competitors." *See Senator Patrick Leahy Press Release; The BLT: The Blog of Legal Times,* February 16, 2011.

NEW BIO BUSINESS VENTURES

UCSF Opens Stem Cell Research Center

The University of California, San Francisco (UCSF) has apparently opened a facility with 25 stem cell labs, funded entirely with private and state money, thus giving scientists the ability to work free from federal restrictions on embryonic stem cells. The $123-million research center, housed in the Ray and Dagmar Dolby Regeneration Medicine Building, opened in early February 2011. *See sfgate.com*, February 9, 2011.

INVESTOR NEWS

Investors Look to Small Biotech Companies as Merger Activity Increases

Portfolio fund managers are reportedly eyeing smaller biotech companies as possible beneficiaries in the wake of a recent merger involving a major drug company and in anticipation of further industry consolidation. "If you're a health-care fund and you have to reinvest, then some of these smaller biotech companies naturally could benefit," a fund manager told a news source.

Noting that many "bellwether names are getting picked off one by one," an analyst predicted that "midcap companies in very early stages of their growth trajectory" might benefit as merger activity increases in health care. Still another analyst noted that "[t]here's going to be very few areas within biotech that people can invest in. I'm expecting the money to spread out. Some of it will end up in pharmaceuticals instead of biotech because they are more diverse and have better value." *See The Wall Street Journal*, February 16, 2011.

Quebec Establishes New Venture Capital Fund to Invest in Biotech Research

Quebec's Charest administration has reportedly launched the third of three new venture capital funds to provide more than $41 million for investment in biotechnology research. Following a new funding model, AmorChem will, according to manager Louis Lacasse, invest "in technologies, rather than companies, in order to avoid investing in expensive infrastructure and having to hire managers. We'll fund them to the point when they can be tested on animals or humans, and then we'll sell it, or license it to a pharmaceutical company."

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.

For additional information on SHB's Biotechnology and Life Sciences capabilities, please contact

Patrick Henderson
Corporate Transactions
816-559-2115
phenderson@shb.com

Madeleine McDonough
Pharmaceuticals &
Medical Device
202-783-8400
mmcdonough@shb.com

Thomas Moga
Intellectual Property
202-639-5622
tmoga@shb.com

If you have questions about this issue of the Report, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

Lacasse has indicated that the projects will involve shared research facilities, and new companies will be created by pooling promising and related projects. "For example, if we have four different molecules that can be used to treat migraines, then we could put together a migraine company, so that if one fails, you have the others to work on. It diminishes the risk."

Funded with both public and private money, AmorChem is viewed as an innovative approach to boost the province's venture capital industry and is expected to provide a benefit for Quebec's universities as well. Other funds recently established are investing in high-tech startups and the clean-tech sector. *See The* (Montreal) *Gazette*, February 19, 2011.

BUSINESS CLIMATE

Study Suggests Investors Optimistic About Biotechnology's Future

The Biotechnology Industry Organization (BIO) and Ipreo have released a study that shows "investors are optimistic on biotech's future and investment in biotechnology will continue to perform well." Providing "in-depth assessment of Wall Street's views on the industry, current challenges, relative valuation, and the outlook for 2011," the study "gathered feedback from 135 investment professionals representing firms with $2 trillion in equity assets under management, including $166 billion invested in healthcare and $38 billion invested in biotech."

Key findings include (i) "more than 86 percent of investors surveyed believe that the major biotech indices will end up in positive territory for 2011, with 35 percent forecasting double digit returns"; (ii) "nearly 55 percent of investors believe that biotech will outperform the rest of the healthcare sector in 2011"; (iii) "investors surveyed are more likely to invest in companies with late stage clinical development versus early stage"; and (iv) "more than 88 percent believe that there are going to be the same or more IPOs [Initial Public Offerings] in 2011 compared to 2010."

"This survey illustrates the long-term confidence that investors have in our industry while detailing the various challenges that impact valuation," BIO's Alan Eisenberg said. Ipreo's Brad Joseph added, "We're pleased to be able to bring this kind of actionable intelligence to biotech companies to help them prepare for meetings and better position themselves to potential investors." *See BIO Press Release,* February 14, 2011.

Ashley Stevens, et al., "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *The New England Journal of Medicine,* February 10, 2011

Concluding that "public-sector research has had a more immediate effect on improving public health than was previously realized," this article finds

that current trends in biotechnology have reversed traditional roles in the development of drugs. Previously, public-sector researchers conducted the basic research that would identify disease mechanisms and potential points of intervention, while the private sector performed the applied research needed to discover, develop and market drug therapies. Some 10-20 percent of all drugs undergoing new-drug applications and approved from 1990 through 2007 involved the contributions of public-sector researchers.

According to this study, "the emergence of biotechnology in the mid-1970s, combined with policy changes implemented in the early 1980s regarding the ownership and management of the intellectual property of [public-sector research institutions], allowed these institutions to play an important role in the downstream, applied phase of drug discovery."

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Administration Budget-Cut Plan Includes Reducing Data Exclusivity for Biologic Drugs

Among other provisions included in President Barack Obama's (D) $3.7 trillion budget proposal is a plan to give biotech drugs seven years of market exclusivity rather than the 12 years already in effect. He has reportedly indicated that the change would reduce health care costs. According to news sources, industry watchers and representatives have criticized the proposal, claiming that it would seriously compromise the ability of biotech companies to recoup their investments and make them less inclined to invest in new drug development. European pharmaceutical interests reportedly expressed concerns that the EU would follow suit in an effort to ease government budgets and reduce health-care costs. They warn that changing the exclusivity period will hamper the development of new drugs.

The Obama administration has also proposed a prohibition on pay-to-delay agreements between brand-name drug makers and generics manufacturers, estimating that this would save $8.8 billion over the next 10 years. Under such deals, brand-name companies pay generic manufacturers that challenge a brand-name patent in exchange for withdrawing the challenge. The Generic Pharmaceutical Association is apparently calling limits on patent settlements "a misguided public health policy initiative." *See San Francisco Business Times*, February 15, 2011; *The Wall Street Journal*, February 16, 2011; and *The Boston Globe*, February 19, 2011.

President Establishes New IP Advisory Committees

President Barack Obama (D) has issued an executive order establishing two intellectual property (IP) enforcement advisory committees. Consisting of federal agency heads or deputies, the "Senior Intellectual Property Enforcement Advisory Committee" will develop a Joint Strategic Plan every three years to

enforce the nation's IP laws. The "Intellectual Property Enforcement Advisory Committee," which will include Senate-confirmed agency personnel involved in IP enforcement, will be responsible for implementing the plan. *See Federal Register*, February 11, 2011.

FDA Expected to Issue Biosimilar Approval Rules in Near Future

Food and Drug Administration (FDA) Commissioner Margaret Hamburg has reportedly indicated that the agency is poised to issue the rules it has developed to review biosimilar medicines, that is, copies of those medicines made from living cells. Discussing the regulatory approval pathway for biosimilars mandated under the health-care overhaul legislation enacted in 2010, Hamburg apparently said during a recent interview, "This is critically important. We obviously have been thinking about this for some time as different models have been discussed and debated. We will be more formally implementing in the very near-term time frame." A key issue is whether the agency will require clinical trials to evaluate biosimilars' effectiveness.

According to a news source, Hamburg said that the agency is not focusing on a new Obama administration proposal, discussed elsewhere in this *Bulletin*, to reduce the data exclusivity period for the makers of biosimilars from 12 to seven years, because the proposal requires congressional action. Hamburg also reportedly declined to indicate when the first biosimilars would be approved under the new procedures. *See Bloomberg*, February 18, 2011.

Joint Public Meeting to Focus on Bridging Nanotechnology Research

The National Nanotechnology Coordination Office has announced that it will spearhead a **public meeting** to focus on "environmental health and safety questions for nanomaterials and nanotechnology-enabled products" and to "encourage joint US-EU programs of work that would leverage resources." The March 10-11, 2011, workshop in Washington, D.C., will also "establish communities of research practice, including identification of key points of contact/interest groups/themes between key US and EU researchers for near-term and future collaborations." *See Federal Register,* February 15, 2011.

FDA Issues Industry Guidance for Drug Co-development

The Food and Drug Administration (FDA) has published draft industry **guidance** for the development of two or more drugs not previously marketed to be used in combination to treat such conditions as cancer, cardiovascular disease or infectious diseases. Noting that the guidelines are not legally enforceable but simply recommendations for industry as it seeks to co-develop drugs, FDA addresses such topics as whether co-development is appropriate, the biological rationale and safety of co-development, clinical development, and regulatory processes.

According to FDA, "The guidance provides recommendations and advice on how to address certain scientific and regulatory issues that will arise during co[-]development. It is not intended to apply to development of fixed-dose combinations of already marketed drugs or to development of a single new investigational drug to be used in combination with an approved drug or drugs. The guidance is also not intended to apply to vaccines, gene or cellular therapies, blood products, or medical devices."

James Doroshow of the National Cancer Institute told a news source that the guidance "clarifies the importance of the need for a sound scientific rationale for the combination and it provides details regarding the types of safety data required from prior Phase I trials. Most importantly, it clarifies the appropriate clinical trial design that could be used for proof-of-concept Phase II studies." *See Nature Review Drug Discovery,* February 2011.

LITIGATION

DOJ Seeks Earliest Calendaring Before Federal Circuit in *Myriad Genetics*

Acting Solicitor General Neal Katyal has requested an April 4, 2011, oral argument date in a case before the Federal Circuit Court of Appeals asking whether and to what extent genetic discoveries may be patented. *The Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Office (Myriad Genetics, Inc.*), No. 2010-1406 (Fed. Cir.). Katyal is apparently also planning to argue the government's position in global warming and health-care reform cases pending before the U.S. Supreme Court and Fourth Circuit, respectively, which arguments are scheduled in April and May. Additional information about *Myriad* appears in Issue 2 of this *Bulletin*. The U.S. Department of Justice contends that genomic DNA isolated from the human body, without further alteration or manipulation, should not be eligible for patents.

NEWS BYTES

The Center for Technology Innovation at the Brookings Institution issues a report titled "Enabling Personalized Medicine through Health Information Technology," that makes recommendations for making the United States a health care leader among those nations "moving forward with personalized medicine and health information technology."

The Center for Law, Science & Innovation at the Sandra Day O'Connor College of Law at Arizona State University (ASU) schedules a national conference to "examine recent trends and challenges in regulation and risk management of nanotechnology." The March 21, 2011, conference in Phoenix will feature national and international nanotechnology experts from government, industry, non-governmental organizations, the insurance industry, and academia.

Shook, Hardy & Bacon L.L.P.

BIOTECH LEGAL BULLETIN

ISSUE 8 | FEBRUARY 24, 2011

Democratic Senators re-introduce a bill (S. 373) to stop brand-name drug makers from marketing authorized generic versions during the 180-day exclusivity window that follows the first successful challenge by a generic-drug manufacturer to a brand patent.

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Intellectual Property & Technology Litigation Associate Jason Mudd will join several panels of distinguished scholars February 25, 2011, for a Missouri Law Review symposium on "Evolving the Court of Appeals for the Federal Circuit and its Patent Law Jurisprudence." The keynote speaker for the event, which will be held at the University of Missouri School of Law in Columbia, Missouri, is U.S. Patent and Trademark Office Director David Kappos. Mudd's panel presentation will focus on "The Court's Impact on Innovation, Industry and the Practice of Law."

Shook, Hardy & Bacon Intellectual Property Partner Peter Strand will lead a session on communicating with jurors at DRI's Business Litigation and Intellectual Property Seminar slated for April 14-15, 2011, in Chicago, Illinois. Titled "A Thousand Words More or Less: Effectively Using Visuals at Trial," the presentation will address "the 'whys' and 'hows' of teaching and persuading jurors using the entire panoply of visual media." ■

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
London, England
+44-207-332-4500
Washington, D.C.
+1-202-783-8400
San Francisco, California
+1-415-544-1900
Irvine, California
+1-949-475-1500
Houston, Texas
+1-713-227-8008
Kansas City, Missouri
+1-816-474-6550
Miami, Florida
+1-305-358-5171
Tampa, Florida
+1-813-202-7100

BIOTECH LEGAL BULLETIN

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.