Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

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IP NEWS

GAO Releases Report on Patent Infringement Litigation and Its Consequences

The America Invents Act (AIA) mandated that the U.S. Government Accountability Office (GAO) conduct a study on the consequences of patent litigation brought by non-practicing entities (NPEs); GAO has concluded that research and recently issued its **report** titled "Intellectual Property: Assessing Factors that Affect Patent Infringement Litigation Could Help Improve Patent Quality." According to GAO, while public discussion focuses on the increasing role of NPEs in patent infringement litigation, NPE lawsuits account for just one-fifth of these cases.

In GAO's view, "regardless of the type of litigant, lawsuits involving software-related patents accounted for about 89 percent of the increase in defendants between 2007 and 2011, and most of the suits brought by PMEs [patent monetization entities] involved software-related patents. This suggests that the focus on the identity of the litigant—rather than the type of patent—may be misplaced." Stakeholders evidently identified three factors likely contributing to many of the recent lawsuits: a prevalence of patents with unclear property rights, i.e., software-related patents often have overly broad or unclear claims or both; large awards from the courts, even where the patents at issue made only small contributions to a product, provide incentives for patent owners to file infringement suits; and companies recognize that patents are a more valuable asset than once assumed. GAO notes that AIA reforms implemented through the judicial system could address some of these issues, but that it may be too soon to determine what effect they will ultimately have on patent litigation.

GAO concludes that an examination of the types of patents and issues in dispute may provide an opportunity to "improve the quality of issued patents and the patent examination process," if the U.S. Patent and Trademark Office would link such trends to internal data on patent examination. A 2003 National Academies report apparently indicated that this type of analysis "could be used to improve patent quality and examination by exposing patterns in the examination of patents that end up in court."

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JOINT VENTURES

U.S. and Japanese Biotechs to Collaborate to Develop Antibody for XLH

Novato, California-based Ultragenyx Pharmaceutical Inc. has entered a collaboration and license agreement with Kyowa Hakko Kirin (KHK), based in Tokyo, to develop and commercialize its experimental therapy, KRN23, a recombinant fully human antibody intended to treat the rare metabolic bone disorder X-linked hypophosphatemia (XLH). Reportedly caused by excessive loss of phosphate in the urine that leads to poor bone growth and a wide variety of bone abnormalities, XLH is the most common heritable form of rickets.

The companies will work together to develop the compound for the United States, Canada and European Union, with Ultragenyx leading the development of KRN23 to treat XLH and both companies sharing development costs. If KRN23 is approved, the companies will share commercial responsibilities and profits in the United States and Canada, while KHK will commercialize KRN23 in the European Union, and Ultragenyx will develop and commercialize KRN23 in Mexico and Central and South America. KHK will manufacture and supply KRN23 for clinical and commercial use globally.

"The collaboration combines Kyowa Hakko Kirin's broad antibody-based discovery, manufacturing and development capabilities with our expertise in the clinical development of novel therapeutics for rare genetic diseases," said Ultragenyx CEO Emil Kakkis. KHK is currently completing a Phase 1/2 extension study in adults with XLH in the United States and Canada, and the companies plan to initiate a pediatric XLH program in 2014. *See Ultragenyx Pharmaceutical Inc. News Release,* September 3, 2013.

INVESTOR NEWS

Biopharmaceutical Raises $45.9 Million for Ear Therapies

Otonomy, Inc., a clinical stage biopharmaceutical company that develops therapeutics to treat ear diseases and disorders, has closed a $45.9-million Series C financing round led by OrbiMed Advisors, LLC and including new investors Aperture Venture Partners and Osage University Partners. The proceeds will reportedly fund late-stage clinical trials for OTO-104, a steroid used to treat vertigo in Ménière's disease patients, and OTO-201, an antibiotic for children with blocked ear canals. The San Diego-based company also plans to develop products that target tinnitus and chronic forms of hearing loss.

"We are pleased to have some of the world's leading healthcare investors participate in this financing led by OrbiMed," said President and CEO David Weber. "Following the successful completion of clinical trials for both of our product candidates, Otonomy is now positioned to complete late-stage trials for both OTO-104 and OTO-201, and further expand our product pipeline." *See Otonomy, Inc. News Release,* September 4, 2013.

Oral Drug Delivery Innovator to Advance Technology with $10 Million in Funding

A company that has developed a platform to convert injectable drugs into pills has reportedly closed a Series B funding round and secured $10 million from Google Ventures and two other venture firms. San Jose, California-based Rani Therapeutics LLC, which claims to have demonstrated double-digit bioavailability in pre-clinical studies, plans to use the funding to support further development of its approach to the oral delivery of large drug molecules including peptides, proteins, antibodies, RNAi therapies, and select vaccines. Rani Chair and CEO Mir Imram said, "We are keenly aware of the magnitude of the problem we are solving, and the potential impact this technology could have on the market." *See PRNewswire*, August 28, 2013.

Israeli Agricultural Tech Firm Secures $65 Million

Kaiima Bio-Agritech Ltd., an Israel-based seed-and-breeding technology company, has completed a $65-million financing round. Three new investors—Horizons Ventures; the International Financial Corp., a member of the World Bank Group; and Infinity Group—joined existing investors in the round. The funding will reportedly support the company's proprietary Enhanced Ploidy technology, which "multiplies [a] plant's genome without compromising its integrity." This non-GMO (genetically modified organism) technology is implemented within vital crop genomes such as wheat, rice and corn, to boost productivity and improve land and water-use efficiencies, according to a company news release.

"By 2050, farmers will be tasked to produce 70% more food than they do today to sustain the growing world population," said Kaiima CEO Doron Gal. "This is a daunting challenge that modern agricultural technology must rise up to meet. The strategic alliance we have formed with our new investors fuels our rapid advances in yield enhancement technology, and positions Kaiima to become an outstanding participant in the global fight against hunger." Kaiima Chair Jeffrey Beard said, "Rather than protect against yield loss, as many GM technologies are designed to do, Kaiima's non-GMO technology is the first since hybridization that actually boosts yield." *See Kaiima Bio-Agritech Ltd. News Release,* September 3, 2013; *Asian Venture Capital Journal,* September 4, 2013.

Pharma Company Raises $26.6 Million for Epigenetic Cancer Therapies

Syndax Pharmaceuticals Inc. has reportedly raised $26.6 million in a Series B financing round for the development of epigenetic therapies targeting treatment-resistant cancers. Preparing for Phase 3 testing, the Massachusetts-based company called its lead product candidate entinostat a promising treatment for breast and lung cancer as both a single agent and in combination with other commercially available therapies. Syndax CEO Arlene Morris said, "We have a unique opportunity to help a patient population where safe and effective treatments capable of extending survival are needed desperately. The Series B financing enables us to continue to advance entinostat toward registration." *See Syndax Pharmaceuticals Inc. Press Release*, August 27, 2013.

BUSINESS CLIMATE

Survey Reveals Effects of Federal Cuts on Scientific Research

According to a **survey** of more than 3,500 U.S. scientists, federal cuts to research funding have resulted in layoffs, a tough labor market for young scientists and a belief that the United States has lost its position as a global leader in scientific research. According to an American Society for Biochemistry and Molecular Biology spokesperson, the data in its report show that "deep cuts to federal investments in research are tearing at the fabric of the nation's scientific enterprise and have a minimal impact on overcoming our national debt and deficit problems." He called for Congress to act "before the damage caused by sequestration is irreversible."

Among other matters, the survey revealed that just 2 percent of respondents have been able to find private funds to make up for those lost from federal grants, more than two-thirds lack sufficient funding to expand their research operations, nearly one-half have laid off researchers, and 55 percent have a colleague who has lost her job. Nearly one-fifth of all respondents said "they were considering moving to another country to continue their scientific career." While the United States invests more real dollars in research and development than any other country, the report said, "[O]f the 10 countries investing the most money in scientific research, the United States is the only country that has reduced its investment in scientific research as a percentage of GDP [gross domestic product] since 2011."

LEGISLATIVE AND REGULATORY DEVELOPMENTS

FDA Claims State Bills Could Threaten Public Confidence in Biosimilars

With legislation requiring pharmacists to notify prescribing physicians that they have filled a prescription with an FDA-approved biosimilar now ready for California Gov. Jerry Brown's (D) approval, the U.S. Food and Drug Administration (FDA) has apparently expressed concern with such state legislation. In a statement released just a few days before the California Senate agreed overwhelmingly to approve the Assembly's S.B. 598 amendments, an FDA spokesperson reportedly said, "Efforts to undermine trust in these products are worrisome and represent a disservice to patients who could benefit from these lower-cost treatments." FDA further noted, "Congress deliberately set a very high bar for a biosimilar product approval." Details about the California bill appear in Issue 63 of this *Bulletin*.

Similar bills are pending before a number of state legislatures; a few have been enacted, despite the federal government's failure to approve any biosimilars to date or to finalize a pathway for regulatory approval. According to a press report, the flurry of legislative activity followed lobbying by the companies that make the biologics for which biosimilars would be substituted. Meanwhile, the Generic Pharmaceutical Association (GPhA) issued a statement about the passage of S.B. 598, claiming that it "would create unnecessary barriers between Californians and newer, lower-cost versions of biologic therapies, known as biosimilars, particularly interchangeable biosimilars." The organization called on the governor to veto the bill. *See BioPharma-Reporter.com*, August 28, 2013; *Law360*, August 29, 2013; *GPhA News Release*, September 4, 2013; *Los Angeles Times*, September 5, 2013.

Pharmaceutical Companies Laud FDA's Breakthrough Drug Approval Procedures

Since the Food and Drug Administration Safety and Innovation Act was enacted in July 2012, the Food and Drug Administration (FDA) has received 82 applications under its new breakthrough therapy designation. Of those, 25 designations have been granted and 32 denied. Pharmaceutical company executives speaking during a recent congressional briefing reportedly praised the new approval tool, which is used for drugs that treat a serious or life-threatening disease and have been shown in preliminary clinical trials to demonstrate substantial improvement on a clinically significant endpoint over available therapies. While the review process is accelerated, with the involvement of senior agency management, approval is not guaranteed, according to FDA's Janet Woodcock. She also apparently noted that the designation can be withdrawn if a better therapy comes to market while the breakthrough drug is still under review. Still, company

representatives reported that a breakthrough designation means that communications typically taking weeks and months can be concluded within minutes. *See Genetic Engineering & Biotechnology News*, September 4, 2013.

Plans for Silicon Valley Patent Office Shelved

According to news sources, entrepreneurs in Silicon Valley are frustrated that plans to establish a satellite U.S. Patent and Trademark Office (USPTO) in San Jose have been shelved, evidently because of the sequestration budget cuts currently imposed on government agencies. Calling the decision to scrap plans for the "promised" office "unique and unfair," area tech leaders said that the satellite patent offices would not be funded by taxpayers, but would have been supported by the $2.8 billion in annual patent fees collected from inventors, entrepreneurs and companies. "We were really upset," said Emily Lam, a director at the Silicon Valley Leadership Group. "It makes absolutely no sense that an office funded almost entirely by fees would be subject to sequester."

According to USPTO CFO Tony Scardino, the government's across-the-board policy does not make exceptions for fee-supported programs, and if there is a "continuing budgetary stalemate" this fall, that could cause further delays. Silicon Valley firms reportedly seek more U.S. patents than any other region in the world, and San Jose is the nation's top patent-producing city, with 7,074 patents in 2012. USPTO currently has a backlog of 590,000 patents nationwide, and satellite offices with patent examiners on site were expected to streamline the application process. Plans for a full satellite office in the area evidently still exist, but for now, Silicon Valley Patent Office Director Michelle Lee, a former Google patent law division head, is working with a few administrative law judges in temporary office space. *See AP.org,* September 1, 2013; *arstechnica.com*, September 3, 2013.

Scientists Seek Trial Release of GM Olive Flies in the EU

Oxford, England-based biotech Oxitec Ltd., has applied for permission to release thousands of genetically modified (GM) olive flies in Spain as an experimental pest-control alternative to chemical pesticides. The trial would reportedly involve the release of a large number of GM male olive flies that would mate with wild female flies. The resulting offspring would be infertile, so the flies, both wild and GM, would fail to proliferate. If it is approved by Catalan and Spanish authorities after a risk assessment, public information period and expert consultation, the trial will be the first of its kind in the European Union (EU).

In theory and controlled greenhouse experiments, the concept has reportedly been successful, with laboratory experiments indicating that the

olive fly population could be eliminated in about two months. If the trials are successful, the scientists hope to test the GM olive flies in British-owned fields in Greece and Italy next.

Critics caution that even when the olive flies are killed, their GM bodies remain and can make their way into food products and the human body. Maintaining that too little is known about the dangers posed by ingesting GM olive flies, Helen Wallace, director of the non-profit environmental group GeneWatch UK, said, "Oxitec's experiments should not go ahead until rules for safety testing and plans for labeling and segregation of contaminated fruits have been thoroughly debated and assessed." *See Oxitec Ltd. News Release,* September 4, 2013; *medicaldaily.com,* September 7, 2013.

LITIGATION

Federal Circuit Applies Pre-AIA Law to Rule It Lacked Jurisdiction to Hear Appeal

The Federal Circuit Court of Appeals has determined that the law in effect before the America Invents Act (AIA) was enacted applied to a dispute filed before that date, and, under the pre-AIA version of 28 U.S.C. § 1295, because the complaint did not arise under patent law, the Federal Circuit lacked jurisdiction to decide whether a district court properly entered summary judgment on patent infringement, an issue raised in the counterclaim. ***Wawrzynski v. H.J. Heinz Co.*, No. 2012-1624 (Fed. Cir., decided September 6, 2013)**. So ruling, the court ordered a transfer of the appeal to the Third Circuit, observing that nothing in federal patent law stood in the way of the plaintiff's pursuit of his state law-based claims.

The issue arose in a case filed by a man who allegedly shared a packaging and marketing concept with a condiment manufacturer that later informed him it was not interested in pursuing his product ideas. After the company released packaging purportedly similar to the plaintiff's concept, he filed a lawsuit against it in state court alleging breach of an implied contract and unjust enrichment. In a counterclaim, the company alleged that it did not infringe the plaintiff's patent and that the patent was invalid. The plaintiff answered the counterclaim by stating that he had not sued the company for patent infringement, and he subsequently covenanted not to sue the company on the basis of the patent. Still, the federal district court, to which the case had ultimately been removed and transferred, granted the company's motion that the state law-based claims were preempted by federal patent law and its motion for summary judgment on its counterclaim of non-infringement.

The Federal Circuit rejected the plaintiff's argument that it could exercise jurisdiction under the post-AIA version of § 1295, which gives federal

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courts jurisdiction over appeals based on a civil action "in which a party has asserted a compulsory counterclaim arising under any Act of Congress relating to patents." According to the court, the date the complaint was filed, and not the date on which the counterclaim was filed, determined whether the AIA version of the law applied.

The court also rejected the defendants' argument that, even under the pre-AIA version of the law, the court had jurisdiction, because, in the company's view, the complaint was based on the plaintiff's assertion of his patent against it. The court found that the complaint (i) did not once use the words "infringe," "infringed," "infringement," "infringer," or "infringing"; (ii) asserted state-law claims and sought state law-based damages; (iii) was not replete with references to the plaintiff's patent; (iv) relied on marketing ideas not included in the patent; and (v) was filed in state court, "not in federal court where he would have filed if he wanted to assert patent infringement."

NEWS BYTES

The U.S. Patent and Trademark Office (USPTO) schedules an America Invents Act (AIA) Second Anniversary Forum for September 16, 2013, in Alexandria, Virginia. This event, which will also be streamed live on the agency's Website, aims to "bring stakeholders together with USPTO subject matter experts to address specific AIA provisions." Among other matters, experts from USPTO's patent business unit and trial and appeal board administrative law judges will focus on "filings made during the past several months with tips for compliance," prioritized examination, preissuance submissions, inventor's oath/declaration, supplemental examination, micro-entity discount, first-inventor-to-file, and administrative trials.

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