

**LIFE SCIENCES
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SCIENCE • TECHNOLOGY
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IP NEWS

Federal Circuit Panel Explores “Exceptional Case” Fee-Shifting Jurisprudence

The Federal Circuit Court of Appeals has returned to a district court an alleged patent infringer’s motion for attorney’s fees to consider whether the patent holder’s legal theory was objectively baseless and then, whether the totality of the circumstances demonstrates that the patent holder acted with subjective bad faith; according to the Federal Circuit, the lower court applied the wrong legal standard in refusing to find the lawsuit exceptional and denying the alleged patent infringer’s request for attorney’s fees under 35 U.S.C. § 285. [*Kilopass Tech., Inc. v. Sidense Corp., No. 2013-1193 \(Fed. Cir., decided December 26, 2013\)*](#). The underlying litigation involved claims that Sidense Corp. infringed Kilopass memory-cell patents both literally and under the doctrine of equivalents. The district court granted Sidense’s motion for summary judgment, and the Federal Circuit affirmed that ruling.

In addition to clarifying the appropriate standards to apply and factors to consider under § 285, the Federal Circuit panel found some merit to Sidense’s arguments in support of changing the standard for assessing exceptionality, including that (i) proof of objective baselessness should be enough to demonstrate exceptionality thus permitting the district court to shift fees in light of the totality of the circumstances, and (ii) alleged infringers should not be required to show exceptionality by clear and convincing evidence, rather, proof by a preponderance of the evidence should be sufficient. The court examined how these legal standards had been derived and concluded that their foundations were weak. Still, the court declined the invitation to change the law, on the ground that, as a panel, it was unable to do so.

Because it was unclear whether the district court required Sidense to demonstrate that Kilopass had actual knowledge that its claims were baseless, which would have been error under the law, and because the district court failed to address the objective merits of Kilopass’s claims by taking into account the totality of the circumstances, the Federal Circuit vacated the judgment denying attorney’s fees.

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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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The factors the lower court will consider, including failure to conduct an adequate pre-suit investigation, vexatious or unduly burdensome litigation tactics, misconduct in procuring the patent, or an oppressive purpose, will likely include findings that Kilopass made claim construction arguments to the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences "that were directly contrary to those being made to the court" thus engaging in "gamesmanship," and attempted to amend its infringement contentions and advance previously undisclosed theories long past applicable deadlines and without court approval.

INVESTOR NEWS

NeXeption Forms New Company to Develop Skin Therapeutics

Malvern, Pennsylvania-based biopharmaceutical management company NeXeption, LLC, has reportedly secured \$21.5 million in Series A financing to form Alexar Therapeutics, Inc. The financing, led by New Science Ventures and Third Point Ventures with participation from Palo Alto Investors, will apparently fund initial development of Alexar's lead compound A-110, a topical liver X receptor agonist for treating skin inflammation disorders. Dave Pfeiffer will serve as CEO and board director of Alexar, and NeXeption Managing Partner Steve Tullman will serve as board chair. "The NeXeption business model allows us to develop promising drug candidates like A-110 by creating and funding independent operating companies that are focused solely on maximizing the value of each asset," said Tullman. *See BusinessWire.com*, January 2, 2014.

Biotech Genocsa Biosciences Files IPO to Fund Vaccine Development

Genocsa Biosciences, Inc. has filed a registration statement with the U.S. Securities and Exchange Commission relating to a proposed initial public offering (IPO) of shares of its common stock. The Cambridge, Massachusetts-based clinical-stage company, which develops novel vaccines through T cell immune responses for infectious diseases such as herpes, chlamydia and malaria, has not disclosed pricing information. Citigroup and Cowen and Co. are listed as joint book-running managers for the deal, with Stifel, Nicolaus & Co. listed as lead manager and Needham & Co., LLC listed as co-manager. The filing follows a September 2013 announcement of "unprecedented" results in a trial of the company's herpes vaccine. Genocsa can evidently identify protective T cell antigens in humans exposed to a pathogen using ATLAS™, its proprietary technology platform. *See Genocsa Biosciences, Inc. News Release*, September 12 and December 23, 2013.

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Cancer Biotech Seeks \$69 Million in IPO

Dicerna Pharmaceuticals, Inc. has [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). Stifel, Jefferies and Leerink Swann are listed as book-running managers on the deal. The Watertown, Massachusetts-based biotech, which develops RNA interference (RNAi)-based drugs to treat cancer and rare diseases, reportedly plans to begin a clinical trial for its first RNAi drug candidate this year. The company's pipeline includes DCR-PH1 to treat primary hyperoxaluria, a liver metabolism disorder, and DCR-M1711 for the treatment of various cancers related to the MYC oncogene, with an initial focus on hepatocellular carcinoma. See *Xconomy.com*, January 2, 2014.

Netherlands-Based Gene-Therapy Company to Go Public

UniQure B.V. has filed a Form F-1 statement with the U.S. Securities and Exchange Commission indicating its intent to convert the legal form of the company under Dutch law from private with limited liability to public with limited liability. Founded in 1998, the biopharmaceutical company hopes to raise up to \$75 million in an initial public offering. UniQure, which develops gene therapies to treat orphan diseases, had its first product approved by the European Commission in 2012 "under exceptional circumstances for the treatment of a subset of patients with lipoprotein lipase deficiency, or LPLD, a potentially, life-threatening, orphan metabolic disease." The company is also developing adeno-associated virus-based gene therapies. Jefferies, Leerink Swann and Piper Jaffray are joint book-runners for the deal. See *nasdaq.com*, January 2, 2013.

BUSINESS CLIMATE**Massachusetts Biotechs Raise Nearly \$900 Million in 2013**

Marking its best year since 2000, the Massachusetts-based early-stage biopharmaceutical industry raised more than \$885 million in initial public offerings (IPOs) in 2013. Of the nine companies that went public, four increased in value and five decreased from the date of the IPO. Still, overall the "class of 2013" reportedly saw a modest average gain of 5 percent as of mid-December 2013. See *Boston Business Journal*, December 17, 2013.

62 Countries Have Biofuel Targets; Algae-Based Crude Closer to U.S. Market

According to the *Biofuel Digest's* annual review of global biofuel mandates and targets, 62 countries either have such goals in place or under consideration. And while some, such as the European Union (EU), have scaled

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back their required renewable fuel content, others will be increasing the percentage of bio-based content over time. The review showed that the bulk of the mandates comes from the EU, but that other major blending mandates anticipated to drive global demand are those established in the United States, China and Brazil. See *Biofuel Digest*, December 31, 2013.

Meanwhile, U.S. government engineers have reportedly found a more economical way to convert wet algae into crude oil, but significant commercialization is still some years away. A news report indicates that the process, which can accommodate a constant algae flow, does not involve drying the algae before it enters a chemical reactor, and byproducts contain enough phosphorus to grow more algae. Lead Department of Energy algae-project scientist Douglas Elliott reportedly said, "We believe that the process we've created will help make algae biofuels much more economical."

Utah-based clean-energy technology developer Genifuel Corp. has apparently licensed the process and hopes to have a pilot plant operational by mid-2014. The amount of acreage required to capture sufficient sunlight as well as the massive water supplies used to grow algae in quantity remain obstacles to commercialization, but major contracts to turn algae into crude have been signed, and it could be on the market by 2018. See *FuelFix.com*, December 27, 2013.

Asia's Biomedical R&D Spend Rises, While U.S. Investment Declines

Researchers have found that the U.S. global share of biomedical research expenditures fell from 51 percent in 2007 to 45 percent in 2012, while China increased its spending by 313 percent, at a compound annual growth rate of 32.8 percent. Justin Chakma, et al., "Asia's Ascent—Global Trends in Biomedical R&D Expenditures," *The New England Journal of Medicine*, January 2, 2014. Noting that the sharp U.S. declines were "driven almost entirely by reduced investment by industry," the researchers report that sequestration of National Institutes of Health (NIH) "funding in 2013 and beyond will exacerbate this reduction by causing U.S. public-sector expenditures to decline." According to the study, NIH "has been a key enabler of the global dominance of the United States in biomedical research and development."

Emergence of Global Nanobiotechnology Industry Explored

According to business and scientific researchers from Australia, Canada and the United States, some 507 firms throughout the world have both biotechnology and nanotechnology capabilities, with the United States in the lead for nanobiotechnology commercialization. Elicia Maine, et al., "The emergence of the nanobiotechnology industry," *Nature Nanotech-*

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nology, January 2014. They explore the development of the industry since the 1980s, noting rapid growth before 2008 and a substantial slowdown since then. They suggest that firms looking to benefit from this emerging industry find ways to enhance the exchange of ideas across technology fields through co-locating diverse groups, “purposeful mixing of disparate expertise and insulation from an incremental innovation culture,” as well as hiring personnel with an interdisciplinary education. The authors also suggest that government influence innovation “by providing resources and by creating an environment encouraging innovation.” Their research showed that star scientists at research universities often seed new biotech clusters.

**LEGISLATIVE AND REGULATORY
DEVELOPMENTS****U.S. House Lawmakers Introduce Personal Drug Importation Bill**

Intended to reduce prescription drug costs for consumers, the “Personal Drug Importation Fairness Act of 2013” ([H.R. 3715](#)) was recently introduced in the U.S. House of Representatives. According to Rep. Keith Ellison (D-Minn.), who introduced the bill on behalf of himself and Reps. Jan Schakowsky (D-Ill.) and Dana Rohrabacher (R-Calif.), allowing consumers to buy prescription drugs from countries with comparable safety standards, “will allow Americans to spend more time focusing on their health and less time worrying about how they’ll pay for their prescriptions.” Each purchase of a drug for importation or reimportation would have to be accompanied by a valid prescription for a supply not exceeding 90 days. The drug would be required to have the same active ingredients, route of administration and strength as a prescription drug approved by the U.S. Food and Drug Administration. *See Rep. Keith Ellison Press Release*, December 13, 2013.

India to Ban PET Packaging for Certain Pharmaceuticals

Citing increasing concerns about potential adverse health effects, the Indian Health Ministry is reportedly considering prohibiting the use of plastic or polyethylene terephthalate (PET) bottles for packaging medicines such as syrups and liquid orals. Despite insufficient scientific evidence linking any health risks to the use of plastic bottles, India’s Drug Technical Advisory Body (DTAB) has suggested that as a first phase the government immediately ban the use of plastic or PET containers in liquid oral formulations for pediatric medicines, geriatric medicines, medicines for women of reproductive age, and medicines for pregnant women.

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According to DTAB, the industry switched away from glass bottles for ease of handling in distribution and retailing, but lacked scientific evidence to show that PET neither leaches endocrine disruptors nor has a harmful effect on drug formulations. In the agency's view, "India has a large variation in temperatures. In summers, the day temperature rises to 40-45 degrees centigrade and the exposure of plastic bottles to such a high temperature may result in adverse effects on the drug formulations packed in plastic bottles." Under DTAB's recommendations, companies would have six months to implement the packaging change. The Drugs Controller General of India will reportedly submit PET bottles containing common medicines to testing. See *BusinessStandard.com*, January 7, 2014.

LITIGATION**SCOTUS Declines to Review Conviction for Clinical Trial Results Misrepresentation**

The U.S. Supreme Court has denied the petition of former biotech executive W. Scott Harkonen seeking review of a Ninth Circuit ruling upholding his conviction for wire fraud based on his alleged issuance of a press release that misrepresented clinical trial results for the drug Actimmune. *Harkonen v. United States*, No. 13-180 (U.S., cert. denied December 16, 2013). According to a news source, the 2002 press release claimed that the drug (i) had decreased the death rate for patients with mild to moderate cases of a fatal lung disease by 70 percent, (ii) was "the only available treatment shown to have clinical benefit," and (iii) would lead to annual sales in excess of \$400 million. Intermune CEO Harkonen was fined \$20,000 and sentenced to three years of probation, a sentence stayed pending appeal. The Bay-area company, which Harkonen apparently left in 2003, reportedly agreed in 2006 to pay \$37 million to settle government claims related to Actimmune's marketing.

Among other matters, Harkonen challenged his conviction on the ground that the government criminalized the expression of a reasonable scientific opinion protected under the First Amendment. In an unpublished ruling, the Ninth Circuit found that the facts supported the jury's finding that Harkonen had the specific intent to defraud in issuing the press release and, because the First Amendment does not protect fraudulent speech, his challenge failed. The Ninth Circuit also denied the government's cross-appeal of the sentence imposed. Harkonen's petition to the U.S. Supreme Court was supported by the Pharmaceutical Research and Manufacturers of America, which filed an *amicus* brief. See *San Francisco Chronicle*, December 16, 2013.

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\$100-Million Tentative Settlement Reached in Meningitis Outbreak from Tainted Steroids

A settlement has reportedly been reached among litigants in multi-district litigation proceedings involving the bankrupt New England Compounding Center (NECC) and its insurers and creditors, including those who allegedly contracted fungal meningitis linked to the compounding pharmacy's tainted injectable steroid products. According to the plaintiffs' steering committee, under the tentative agreement, which requires additional negotiation as well as court approval, a compensation fund potentially exceeding \$100 million would be created for distribution to "victims and their families as compensation for the deaths, injuries and suffering they endured as a result of this tragic meningitis outbreak." Plaintiffs' counsel also noted that litigation would continue separately against clinics, doctors, hospitals, and NECC vendors allegedly at fault. The next court hearing in the matter is scheduled for January 10, 2014. See *Business Wire*, December 23, 2013; *Reuters*, December 24, 2013.

NEWS BYTES

The U.S. Patent and Trademark Office [schedules](#) a January 14, 2014, public forum in Alexandria, Virginia, "to discuss implementation of Title I of the Patent Law Treaties Implementation Act of 2012." The law, which serves as the implementing legislation for the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs (the Hague Agreement), allows applicants to file single international design applications to acquire global protection. The forum will be available via Webcast.

The U.S. Patent and Trademark Office [extends](#) a pilot program "in which an applicant, under certain conditions, can request a twelve-month time period to pay the search fee, the examination fee, any excess claim fees, and the surcharge (for the late submission of the search fee and the examination fee) in a nonprovisional application." The agency's "Extended Missing Parts Pilot Program," which permits applicants additional time to determine if patent protection should be sought thus allowing them to focus on commercialization efforts during the time period, will run through December 31, 2014.

UPCOMING CONFERENCES AND SEMINARS

The Product Quality Research Institute, U.S. Pharmacopeial (USP) Convention and American Association of Pharmaceutical Scientists have [scheduled](#) a nanotechnology workshop for January 14-15, 2014,

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at the USP Meeting Center in Rockville, Maryland. Titled "Nanomaterial Drug Products: Current Experience and Management of Potential Risks," the workshop will feature presentations by industry representatives, academics and government regulators.

Slated for January 22, 2014, from 1-2:30 p.m. (EST), [The Sedona Conference® Webinar on "Patent Litigation Best Practices: A Matter for Congress or for Bench and Bar?"](#) will feature a panel of corporate practitioners and judges who will discuss proposed patent-reform legislation that would change litigation procedures, provide for fee-shifting and impose heightened pleading standards. Topics to be addressed during the Webinar include (i) "pending legislative bills and their likely impact, intended or otherwise, on the quality and efficiency of patent litigation, and the enforceability of intellectual property rights"; (ii) "the effect these bills would have on the level of discretion federal judges could exercise in managing patent cases"; and (iii) "whether the legislative concerns underlying these bills can be addressed by the Patent Pilot Program and the development of patent litigation best practices by those in the field."

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