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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Legal Malpractice Arising from Patent Suit Belongs in State Court, Says SCOTUS

The U.S. Supreme Court has determined in a unanimous decision that the federal courts do not have jurisdiction over a legal malpractice claim arising from a patent dispute. ***Gunn v. Minton*, No. 11-1118 (U.S., decided February 20, 2013)**. So ruling, the Court reversed the Texas Supreme Court which concluded that the matter belonged in federal court because the success of the disappointed client's malpractice claim relied on a question of federal patent law, i.e., whether a patent law defense first raised on appeal would have succeeded, thus allowing the client to hold his attorney liable for failing to timely raise the issue. Additional information about the case appears in Issues **44** and **47** of this *Bulletin*.

The U.S. Supreme Court applied the following test to reach its decision: "federal jurisdiction over a state law claim will lie if a federal issue is: (i) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." According to the Court, "it is clear that Minton's legal malpractice claim does not arise under federal patent law. Indeed, for the reasons we discuss, we are comfortable concluding that state legal malpractice claims based on underlying patent matters will rarely, if ever, arise under federal patent law for purposes of [28 U.S.C.] § 1338(a). Although such cases may necessarily raise disputed questions of patent law, those cases are by their nature unlikely to have the sort of significance for the federal system necessary to establish jurisdiction."

The Court found that the Texas Supreme Court mistakenly focused on "the importance of the issue to the plaintiff's case and to the parties before it." To the contrary, the "substantiality inquiry under *Grable* looks instead to the importance of the issue to the federal system as a whole." In the Court's view, a state court resolving a "case within a case" issue touching on patent law "will not change the real-world result of the prior federal patent litigation."

Nor would a state's "case within a case" patent rulings bind federal courts. The disappointed client here lost his patent validity claim in federal court and lost his malpractice suit in state court. The case was returned to the Texas Supreme Court for further proceedings.

SCOTUS Hears Argument on Patent Exhaustion in GE Seed Case

According to court watchers, the U.S. Supreme Court appeared skeptical of claims by an Indiana farmer that the first sale of a genetically engineered (GE) seed exhausts the patent rights to it. ***Bowman v. Monsanto Co.*, No. 11-796 (U.S., argued February 19, 2013)**. Additional details about the case appear in Issue **22** of this *Bulletin*.

The patent owner brought a patent infringement suit against farmer Hugh Bowman who openly planted GE soybean seeds from commodity seed he purchased from a local grain elevator for planting as a late-season crop. He also saved seeds from his late-season crop to plant again as a late-season crop. The Federal Circuit Court of Appeals determined that farmers who plant the progeny of GE seeds protected by U.S. patents infringe those patents even where the progeny are derived from commodity seed. According to the court, even if the patent rights are exhausted in the commodity seeds (which are generally used as animal feed), when a grower plants those seeds "and the next generation of seeds develops, the grower has created a newly infringing article."

Chief Justice John Roberts apparently asked why any company would invest millions of dollars to create a new seed if a farmer can buy one and reproduce it at will. The Court seemed to consider that patent holders do not exhaust their rights after selling products which can be easily copied or copy themselves. Justices Sonia Sotomayor and Antonin Scalia agreed that farmers can use patented seeds to plant a crop but cannot grow additional seeds as part of that crop for later use. Sotomayor said, "The exhaustion doctrine allows you to use the good you buy. It never permits you to make another item."

According to Columbia Law Professor Ronald Mann, the stakes in the litigation are high, particularly from the perspective of the information technology industry. "If the Court rules against Monsanto on the basic exhaustion question, it then must confront the controversial question (crucial to, among others, the software industry) of the enforceability of license agreements that govern the rights of users of IP-infused products." Mann predicts that the Court will not rule against the patent holder. *See SCOTUS Blog,* February 18, 2013; *LATimes.com*, *Associated Press, The National Law Journal,* and *Greenwire*, February 19, 2013.

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INVESTOR NEWS

New Company Launched with $47 Million to Develop Cancer Immunotherapies

According to news sources, Massachusetts-based venture capital firm Third Rock Ventures has made a $47-million Series A financing commitment to launch Jounce Therapeutics, Inc., a cancer immunotherapy developer. Apparently, Jounce's capabilities and expertise include tumor immunobiology, antibody discovery and optimization and integrated translational science capabilities, including *in vivo* tumor model systems and other clinically based approaches. Although many companies have apparently tried and failed to deliver on the promise of immunotherapy, which harnesses the body's immune system to reject or attack cancerous cells and tumors, sources indicate that recent advances in the field show that immunotherapy could potentially become a standard approach for fighting various cancers.

Interim CEO of Jounce and partner at Third Rock Ventures Cary Pfeffer said, "Our goal at Third Rock Ventures is to launch and build companies that dramatically impact and improve patients' lives. Cancer immunotherapies have shown the potential to not just incrementally enhance patients' quality of life, but to significantly improve their long-term survival. Jounce has assembled a world-leading team that is at the forefront of the new understanding of the power and potential of cancer immunotherapies. We are uniquely positioned to rapidly develop our pipeline and, ultimately, deliver on our goal of improving patients' lives." Jounce was reportedly founded by world leaders in immunobiology, cancer biology and clinical and translational medicine. *See BusinessWire.com* and *Xconomy.com,* February 14, 2013.

BIND Biosciences Secures $8.7 Million to Develop Cancer Drug

Massachusetts-based BIND Biosciences Inc., which develops nanoparticle technology that concentrates a drug directly at the site of cancer cells (and purportedly minimizes exposure to healthy tissue and decreases side effects), has reportedly secured $8.7 million in equity financing. According to CFO Andrew Hirsch, "Proceeds from the financing will be used to fund Phase 2 clinical studies of BIND's lead drug candidate, BIND-014, a PSMA-targeted Accurin containing docetaxel, in multiple solid tumor indications. Based on preclinical and clinical studies to date, the company believes there is potential for BIND-014 to offer a significant improvement in patient outcomes in a broad range of solid tumor indications. In addition, the company plans to continue to advance the capabilities of its nanomedicine platform for novel Accurins, including identifying further opportunities for proprietary drug candidates as well as pursuing collaborative drug development programs with pharmaceutical and biotech partners."

BIND is reported to have received $47.35 million financing from RUSNANO—a billion dollar investment fund owned by the Russian government and focused on nanotechnology—existing investors and new investors in October 2011. *See Boston Business Journal,* February 12, 2013; *FierceBiotech.com,* February 13, 2013.

Multiplicom NV Receives €5.5 Million to Develop Genetic Diagnostic Tests

Multiplicom NV, a Belgium-based start-up company that specializes in molecular diagnostics, has apparently raised €5.5 million, which the company reports will be used to develop further diagnostic tests, fund international validation studies and expand its European sales channels. In 2012, Multiplicom received CE certification for its test to detect genetic defects that might indicate an increased risk of ovarian cancer or breast cancer. The company also reports that it is planning to introduce a new series of kits that can detect DNA mutations in cancerous tissue in 2013.

Multiplicom develops, produces and sells genetic tests based on molecular diagnostic technologies that help identify increased genetic risk to develop a disease, detect congenital defects at an early stage and determine the most suitable therapy for patients, according to a company press release. Company backers include Flemish investment company PMV, RMM and Qbic ARKIV Fund as well as existing investors Gimv (Biotech Fonds Vlaanderen) and VIB.

Multiplicom CEO Dirk Pollet said, "This capital injection will allow us to carry out our ambitious plan to develop innovative molecular diagnostic kits and to remain at the forefront of European businesses in this new branch of medicine."

BUSINESS CLIMATE

Biopharma Industry Survey Reveals Talent Shortage

A new report based on a CEO survey reportedly cites a talent gap in the scientific workforce that has the U.S. biopharmaceutical industry taking new approaches to research and development (R&D) staffing. The PricewaterhouseCoopers Health Research Institute study apparently shows that about half of the executives surveyed report difficulties hiring and fewer than 30 percent were confident they will be able to access top talent. Nearly three-fourths reportedly indicated their intention to hire in 2013. Outside partnerships are evidently one of the alternative methods used to boost R&D productivity—the most common are partnerships with academic medical centers and third parties, including contract research organizations. A few companies are even partnering with traditional competitors through consortia and foundation alliances. According to the report, the most-needed skill anticipated during the next three years will be an ability to develop and manage outside partnerships. *See Online PharmaTimes*, February 5, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Final Rule Issued on First Inventor to File System Under Patent Reform Law

The U.S. Patent and Trademark Office (USPTO) has issued a **final rule** to implement the first-to-file provisions of the Leahy-Smith America Invents Act (AIA). It takes effect March 16, 2013. Among other matters, USPTO has added definitions to the rules of practice and otherwise clarified AIA provisions that treat "U.S. patents and U.S. patent application publications as prior art as of their earliest effective U.S., foreign, or international filing date"; eliminate "the requirement that prior public use or sale be 'in this country' to be a prior art activity"; and treat "commonly owned or joint research agreement patents and patent application publications as being by the same inventive entity for purposes of novelty, as well as nonobviousness."

USPTO has also published **guidelines** for office personnel "to assist in the implementation of the first inventor to file provisions of the AIA." The *Federal Register* notice includes comments submitted on the proposed guidelines and USPTO's responses. *See Federal Register*, February 14, 2013.

Support Growing for Request That FDA Freeze Biosimilar Applications

The Washington Legal Foundation (WLF), a public interest law and policy center, has filed **comments** with the U.S. Food and Drug Administration (FDA) supporting a citizen petition which claims that FDA's use of safety and effectiveness data, submitted by sponsors of reference biological products before March 2010, to approve a biosimilar product constitutes an unconstitutional "taking" under the Fifth Amendment. In March 2010, Congress created a pathway for the approval of biosimilars when it enacted the Biologics Price Competition and Innovation Act. Under the Act, a biosimilar applicant is not required to show that its product is safe and effective; rather, it must simply show that the product is biosimilar to a reference product.

WLF argues that FDA use of reference product application data "to approve the products of competitors constitutes an infringement of the property rights of the firm that submitted the data." According to WLF, "firms that submitted their [biologic licensing applications] prior to adoption of the [Act] had a 'reasonable investment-back expectation' that the federal government would not take actions to destroy the value of their trade secrets. Use of the trade secrets to approve a competitor's product would destroy their value." Thus, reference product sponsors submitting data before March 2010 are, in WLF's view, entitled to "just compensation," if FDA uses their data to approve any biosimilar.

Because Congress did not provide for the "payment of Takings Clause compensation to the sponsors of approved [biologic licensing applications]," WLF contends that "Congress did not authorize FDA to approve biosimilars based on any reference product whose sponsor was given assurances that its trade secrets would not be used to benefit others."

While the issue may not yet be justiciable, given that FDA has yet to receive an application to approve a biosimilar product, if the petition succeeds, U.S. entry into the biosimilar field could be delayed until 2022. Biologics are complex drugs that cannot be reverse-engineered to create a generic version, i.e., a biosimilar. The Act allows FDA to rely on reference product data in its approval of a biosimilar, but only after the biologic has been on the market for 12 years. According to WLF, biologic license applicants who have filed since March 2010 knew that their trade secrets could thereafter be used by FDA to approve competitors' biosimilar products and would not be protected under the Takings Clause. Biologic drug makers may face competition from abroad as other countries have already adopted biosimilar approval pathways. *See WLF Press Release*, February 13, 2013; *BioWorld.com*, February 15, 2013.

IOM Publishes Report on the Effects of Falsified and Substandard Medicines

At the request of the U.S. Food and Drug Administration (FDA), national think tank the Institute of Medicine (IOM) has published a **report** that identifies the global public health implications of falsified, substandard and counterfeit pharmaceuticals and recommends a range of strategies to address the problem and promote global dialogue and action. Titled "Countering the Problem of Falsified and Substandard Drugs," the report notes that it is "difficult to measure the public health burden of falsified and substandard drugs, the number of deaths they cause, or the amount of time and money wasted using them," and contends that "tackling this global problem requires international cooperation, but disagreements … have hampered coordinated efforts."

Among other things, the report suggests "strengthening regulatory systems; adding inspectors to police wholesalers, distributors and manufacturers; enforcing quality standards; and licensing only those manufacturers that meet international standards." It concludes by stating that "Stakeholders around the world share a common interest in combating inferior-quality drugs. At the international level, productive discussion relies on cooperation and mutual trust."

In an agency press release, FDA commended the report for "its thorough discussion and recommendations," and says that it "recognizes that all countries need to work together to ensure safe medicinal products for their citizens due to the

increasing complexity of the global economy." FDA also says that it remains "committed to engaging with multiple stakeholder groups to advance global solutions and minimize exposure of consumers to unsafe products."

To meet the challenges of today's global marketplace, FDA says that it "is transforming from a predominantly domestically focused agency to one that is fully prepared to help ensure product safety and quality within a globalized world," and notes that many of the IOM recommendations support actions and efforts are already underway at the agency, including advancing technology, strengthening global regulatory capacity, strengthening surveillance, developing science-based standards, and engaging in global dialogue. *See FDA Press Release,* February 13, 2013.

FDA Considers Changes to Generic Drug Labeling Rules

A footnote in an *amicus* brief filed by the U.S. Department of Justice (DOJ) in a case involving whether a design-defect claim asserted against a generic drug maker is preempted by federal law reportedly indicates that the U.S. Food and Drug Administration (FDA) has informed DOJ that it is considering a regulatory change that "would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances." If FDA takes such action, it would moot a 2011 U.S. Supreme Court ruling that generic manufacturers cannot be held liable for failing to strengthen their labeling even when they knew about side effects because current rules do not allow them to do so.

Georgetown University Law Professor Brian Wolfman, who signed a Public Citizen petition asking FDA to allow generic drug makers to change their labels thus giving consumers allegedly injured due to inadequate warnings the ability to bring state law-based personal injury actions against them, said that the footnote indicates FDA's commitment to fully vet the petition. "I don't think the solicitor general would say that unless they were giving it serious consideration, because to do anything else would be seriously misleading," Wolfman said. *See Pharmalot* and *Law360*, February 11, 2013.

Drug Makers Complain About Slow Regulatory Approvals in India

Pharmaceutical companies have reportedly begun shifting their clinical trials out of India, claiming that bureaucrats have been slow to approve them and that a lack of clarity on how to conduct the trials has engendered regulatory uncertainty. A case before the Supreme Court charging the companies with using poor people as "guinea pigs" to test unsafe drugs without their consent or appropriate state scrutiny has apparently made government officials more cautious about approving new trials. While it is apparently taking 6-8 months

to initiate a clinical trial in India now, it takes just 28 days in Europe and Canada. Global drug makers are also reportedly turning to Russia and Brazil to test their new products. The relatively low costs of testing drugs in India, which drew the companies there, cannot evidently outweigh the approval delays. *See Reuters*, February 12, 2013.

State Momentum to Restrict Use of Biosimilars Slows

Legislation in Mississippi that would have allowed pharmacists to substitute biosimilars only if they are deemed interchangeable with the prescribed biologic medicine for the specified indicated use by the U.S. Food and Drug Administration (FDA) has reportedly failed. More than 12 state legislatures are apparently considering similar bills that would restrict biosimilar substitution. The issue pits biopharmaceutical makers against pharmacists and chain drug stores which support automatic substitution of interchangeable biosimilars and contend that when FDA approves a biosimilar, pharmacists should be allowed to automatically substitute it under the Public Health Service Act. Meanwhile, a bill that would require physician notification when a pharmacist makes such a substitution has reportedly cleared its first legislative committee in Colorado. *See Pharmalot*, February 8, 2013; *bizjournals.com*, February 12, 2013.

LITIGATION

Federal Circuit Affirms Dismissal of Patent Assignor Estoppel Claims

The Federal Circuit Court of Appeals has affirmed the district court's dismissal of claims filed by a patent owner against the co-inventor who assigned his rights to the patent to the owner's founder and, in the patent owner's subsequent patent infringement litigation, agreed to assist the defendant by repudiating his signature on the assignment documents. ***Semiconductor Energy Lab. Co., Ltd., v. Nagata*, No. 2-12-1245 (Fed. Cir., decided February 11, 2013)**.

According to the court, the patent owner sought to apply the doctrine of assignor estoppel as an offense, claiming that the inventor's allegedly wrongful conduct involved the resolution of one or more substantial questions of federal patent law. The court disagreed, finding that (i) the doctrine of assignor estoppels is an affirmative defense, "not a claim for relief on its own"; (ii) the district court did not err in ruling that the complaint failed to state a claim arising under federal law; and (iii) the remaining state law claims are independent of the "contrived federal issue" and are "separately supported by alternative state law theories that do not necessarily require resolution of any disputed substantial question of federal patent law."

In light of the U.S. Supreme Court's *Gunn v. Minton* ruling, summarized elsewhere in this *Bulletin*, it is unlikely that the Federal Circuit's ruling would be overturned if the patent owner sought review and the Supreme Court agreed to review it.

Eighth Circuit Says Pleadings Can Be Filed Under Seal, But Needs More Justification

The Eighth Circuit Court of Appeals has determined that a federal district court did not abuse its discretion in sealing an antitrust complaint involving parties that were litigating patent infringement claims against each other; the court, however, returned the matter to the lower court for an assessment as to whether the redaction of confidential business information is practicable and an explanation as to why the entire complaint should remain under seal, if the court again denies the motion to unseal. ***IDT Corp. v. eBay*, No. 11-3009 (8th Cir., decided February 11, 2013)**.

According to the court, the district court "properly treated as minimal the public's interest in access to this antitrust complaint. … The complaint in this case 'play[ed] only a negligible role in the performance of Article III duties.' … The court never adjudicated any aspect of the claims on the merits" because the antitrust action, as well as the two patent suits out of which it arose and over which the district court had presided, were settled by the time the Arkansas Public Law Center sought to intervene in the antitrust matter and filed its motion to unseal the complaint.

NEWS BYTES

The U.S. Patent and Trademark Office **schedules** a series of public roundtables "to solicit stakeholder input on ways the agency can reduce the number of Request for Continued Examination (RCE) filings." The sessions began February 20, 2013, in California, and will end March 8 in Chicago.

The U.S. Food and Drug Administration's (FDA's) Cincinnati District **announces** a March 12-14, 2013, public conference at Xavier University to explore issues relating to pharmaceutical quality in a global supply chain. Speakers include key FDA officials, global regulators and industry representatives.

The U.S. Food and Drug Administration **requests** comments "on certain questions related to drug and biological product shortages" on or before March 14, 2013. The comments will aid the agency "in drafting a strategic plan on drug shortages."

The U.S. Food and Drug Administration **extends** the comment period for a draft environmental assessment and a preliminary finding of no significant impact relating to a new animal drug application for a genetically engineered

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Atlantic salmon. The documents were made available in a December 26, 2012, *Federal Register* notice. The new comment deadline is April 26, 2013.

The U.S. Food and Drug Administration (FDA) **issues** draft guidance describing "the accreditation, reaccreditation, and accreditation withdrawal process, including criteria that will be considered to accredit, reaccredit, deny accreditation to, and deny reaccreditation to third party reviewers under the Third Party Review Program" relating to premarket review of medical devices. The guidance is based in part on a draft document prepared by the International Medical Device Regulators Forum, which intends to finalize its guidance at the end of 2013. Comments on FDA's document are requested by April 16. ■

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