Shook, Hardy & Bacon L.L.P.

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BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

Despite Public Patent Application, Trade Secrets Claims Can Proceed

The Fifth Circuit Court of Appeals recently determined that the owner of trade secrets relating to a meat-packing method can pursue misappropriation claims even though some of those secrets were previously published in a patent application. ***Tewari De-Ox Sys., Inc. v. Mountain States/Rosen, L.L.C., No. 10-50137 (5th Cir., decided April 5, 2011)***.

A lower court ruled that the plaintiff's 2004 patent application disclosed the method and destroyed the company's trade secrets or that the elements were known in the industry. The Fifth Circuit, however, noted that the plaintiff customized its processes to the defendant's operations and equipment when it demonstrated the method to the defendant under a non-disclosure agreement in 2005. According to the court, "a trade secret can exist in a combination of characteristics and components each of which by itself is in the public domain[;] the unified process, design and operation of [that] unique combination affords a competitive advantage and is a protectable secret." The defendant argued that a simple and obvious change in an existing device or process is not a trade secret, and the court agreed, but said this was an issue of fact for the jury to determine.

The court reversed the lower court's grant of the defendant's motion for summary judgment and remanded the case for further proceedings.

INVESTOR NEWS

India Biotech Sector Set to Reach $10 Billion by 2015

According to a news source, India's biotechnology sector is expected to reach $10 billion in revenue by 2015. A top state official has claimed that innovative biotech products and services brought $4 billion in fiscal 2011, with the state of Karnataka contributing $1.6 billion, or 40 percent of the nation's total.

India is reportedly ranked among the top 12 biotech destinations worldwide and third largest in the Asia-Pacific region. To ensure that Karnataka remains a major biotech industry investment destination, the state government has evidently set up a $10-million Bio Venture Fund to help startups in high-technology areas. *See The Economic Times,* May 5, 2011.

AborGen IPO Plans Change

With a federal district court in Florida apparently poised to issue a ruling on whether the U.S. Department of Agriculture (USDA) complied with environmental laws in approving open-air field tests of genetically engineered (GE) eucalyptus trees, AborGen, the company that developed the "cold-tolerant" hybrid, has reportedly aborted plans to sell its shares on the NASDAQ exchange. AborGen hopes to commercialize the GE tree for pulp and biofuel production.

A coalition of environmental organizations filed the lawsuit in July 2010, claiming that USDA ignored significant environmental risks in approving the field tests, which were to be conducted at multiple sites across the southeastern United States.

The plaintiffs allege that the hybrid uses water at a rate at least twice that of native forest stands in the region and could pose a risk of gene flow, "which would seriously disrupt native ecosystems."

According to news sources, the biotech industry has acknowledged the chilling effect such litigation has had on product development. A spokesperson for the Biotechnology Industry Organization was quoted as saying, "Obviously, the litigious environment we have seen in the past couple years is representing a tremendous deterrent to investment in [biotechnology]. It's making it very hard to get investments and to see their way through what could be five and 10 years in development of a product, if when you finally do get to a point where you're close to commercialization, you're going to have to deal with litigation. It is creating a huge barrier." *See Global Research*, May 13, 2011.

Biotech Secures $7 Million in Series B Financing for Phase 1b Clinical Trials

Prexa Pharmaceuticals, which is developing therapies for central nervous system (CNS) diseases and disorders, has announced that it has obtained $7 million in Series B financing. Advent Healthcare Ventures led the round, with Shire Pharmaceuticals included as a new investor. According to Prexa, the proceeds will help complete "IND-enabling studies through Phase 1b clinical studies for its lead product candidate PRX-12251," which is a triple reuptake inhibitor that blocks dopamine, norepinephrine and serotonin transporters.

Founded in 2006, Prexa says it is working to enhance dopamine and norepinephrine activity to improve the safety and efficacy of current ADHD, depression and Parkinson's disease treatments. "We are targeting indications

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that we believe have an unmet need," said Prexa CEO Charles Cohen. *See Prexa Pharmaceuticals Press Release,* May 11, 2011.

BUSINESS CLIMATE

Report Examines Economic Impacts of Human Genome Project

A new report claims that the $3.8 billion the U.S. government invested over a 15-year period on the Human Genome Project (HGP) has triggered $796 billion in economic activity. Produced by Cleveland-based Battelle Memorial Institute, the report says that the genome-sequencing project also spurred a new life-sciences industry that now drives $67 billion yearly in economic output and supports 310,000 jobs.

Started in 1988 and completed in 2003, HGP was a U.S.-led international effort that sequenced the human genome, that is, determined the complete sequence of the 3 billion DNA base pairs and identified each human gene. The project fostered economic activity such as the manufacture of sequencing machines, genetic test kits and diagnostic materials for lab experiments, said Battelle, a nonprofit dedicated to scientific research. "One surprise is that the genome-based industry that exists today is larger than we expected," Simon Tripp, a Battelle economist and report co-author, told a news source.

Funded by Life Technologies, a California-based biotech company, the study has reportedly drawn criticism by some economists who question its methodology. "What they did is conventional and reasonably done, for what it is," Ohio State University economist Bruce Weinberg was quoted as saying. "But at a deeper conceptual level, it's not very consistent with economic logic. All those guys who wound up sequencing the genome? Those aren't the benefits, those are the costs of sequencing the genome." *See Battelle News Release, The Wall Street Journal* and *Scientific American,* May 11, 2011.

MoneyTree™ Report Shows Increased Life Sciences Investments in Q1 2011

According to a PricewaterhouseCoopers report on venture capital investments, although fewer deals occurred in the first quarter of 2011 (Q1 2011) as compared to the last quarter of 2010, investment activity increased 5 percent overall. The *MoneyTree*™ Report, which is based on data provided by Tomson Reuters, ranked biotechnology third among industry sectors, representing $784 million in investments for 85 deals out of a total $5.8 billion invested in Q1 2011. The most active regions for venture capital investment are the Silicon Valley, New England, New York City Metro, Los Angeles/Orange County, and Midwest.

Tufts Study Claims Biotech Drug Approvals Nearly Double in Last Decade

Data from a Tufts Center for the Study of Drug Development (CSDD) study indicate that U.S. regulatory approvals for new biopharmaceuticals have nearly doubled in the last decade compared to the 1990s. From 2000 to 2009, 65 biopharmaceutical products received FDA approval, up from 39 in the 1990s and 13 in the 1980s, according to the study published in the May/June 2011 *CSDD Impact Report*.

"While the strong growth in approvals is positive news for biotech companies and patients alike, biopharmaceutical development remains complex and developers face substantial challenges if they are to continue winning approvals of the last decade," Tufts University assistant professor and study author Janice Reichert was quoted as saying.

Noting that average, combined clinical and approval phase time for biopharmaceuticals rose to 95 months for the 2000s, up from 77 months in the 1990s, Reichert reported that (i) "recombinant protein products as a share of all new biopharmaceuticals approved by the FDA increased slightly, from 54% in the 1980s to 57% in the 2000s"; (ii) "new biopharmaceutical approvals in the 2000s were more evenly distributed in six therapeutic categories, compared to those of 1980-89 and 1990-99"; and (iii) "neither orphan nor fast track designation had a substantial impact on the average time from initiation of clinical study to FDA marketing approval for new biopharmaceuticals approved in the 2000s." *See Tufts CSDD Press Release,* May 10, 2011.

North Carolina Life Sciences Companies Attract More than $1.1 Billion in Investments, Grants

After conducting its yearly **survey** of media reports, a North Carolina trade association has announced that life sciences companies brought in more than $1.1 billion in investments and grants to the state in the 12 months ending April 25, 2011, representing a 25 percent increase over the 12-month period ending April 2010.

The North Carolina Biosciences Organization (NCBIO) conducts the survey in conjunction with an annual briefing for state legislators.

According to NCBIO, the life sciences funding includes equity investments, licensing payments, grants, and investments in building and equipment that totaled $924 million. Equity investments reportedly totaled $446 million, building and equipment totaled $437 million, grant announcements totaled $126 million, and licensing payments totaled $122 million.

"These payments represent cash flowing directly into our state for jobs in life science innovation," said NCBIO President Sam Taylor. "The survey reaffirms the economic impact of North Carolina's life sciences cluster, which the

North Carolina Biotechnology center has estimated generates $46.6 billion in economic activity annually, and supports employment for more than 226,000 North Carolinians." *See NCBIO Press Release,* April 28, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

USDA Establishes 50,000 Acres in Midwest for Biofuels Crops

The U.S. Department of Agriculture (USDA) has announced it will designate 50,000 acres in 39 contiguous Kansas and Missouri counties "for the production of dedicated feedstocks for bioenergy." Representing the first Biomass Crop Assistance Program (BCAP) Project Area, the designation will help foster development of next-generation biofuels, according to USDA.

By establishing a dedicated crop of native grasses and herbaceous plants for power and heat generation, the project—a joint Missouri's Show Me Energy Cooperative and USDA effort—aims to "spur expansion of domestically produced biomass feedstock in rural America for renewable energy." Created in the 2008 Farm Bill, BCAP was designed to reduce U.S. reliance on foreign oil, improve domestic energy security, reduce pollution, and spur rural economic development and job creation.

Teams of crop producers and bioenergy facilities are invited to submit proposals to USDA to participate in the program for reimbursements of up to 75 percent of the cost of establishing a bioenergy perennial crop, up to five years of annual payments for grassy crops and up to 15 years of annual payments for woody crops. USDA advises producers interested in participating to visit their local Farm Service Agency county office. *See USDA Press Release,* May 5, 2011.

FDA Requests Input on User Fees for Biosimilar, Interchangeable Biological Products

FDA has issued a **notice** requesting comments relating to the development of a user fee program for biosimilar and interchangeable biological product (351(k)) applications for fiscal years 2013 through 2017.

The agency defines biological products as those "produced in a living system such as a microorganism, plant, or animal cell," as opposed to small molecule drugs made through chemical synthesis. Comments are requested by June 9, 2011.

According to FDA, the Biologics Price Competition and Innovation Act of 2009 "creates an abbreviated approval pathway for biological products that are demonstrated to be highly similar (biosimilar) to or interchangeable with an FDA-licensed biological product." The agency's user fee recommendations must be presented to Congress by January 15, 2012. *See FDA Press Release,* May 9, 2011; *Federal Register,* May 10, 2011.

In a related development, FDA reportedly plans to issue guidance this year for those companies seeking market approval for biosimilar drugs. Janet Woodcock, head of FDA's Center for Drug Evaluation and Research, told a news source that biosimilars' individual characteristics require specific regulations and that human testing will not be a blanket requirement. "It depends on how confident you can be of the absolute sameness to the innovator product," she was quoted as saying. "There's a spectrum … some will get much closer than others in your ability to characterize them." She also said that FDA has yet to receive any biosimilar applications, but "we are open for business right now." *See Reuters,* May 9, 2011.

Pharma Trade Group Seeks Biologics Data Exclusivity for International Trade

PhRMA has reportedly called for the U.S. Trade Representative to go outside provisions in the Korea-U.S. trade deal (KORUS) and press for a 12-year period of exclusivity for biologics in ongoing Trans-Pacific Partnerships (TPP) negotiations. While drug manufacturers usually seek replication of the KORUS patent provisions, considered a "gold standard" for IP protections, in the TPP context, KORUS does not include the 12-year mandate because it was not part of U.S. law when KORUS was negotiated. Brand-name pharmaceutical companies support 12 years of exclusivity saying it is needed to recover research and development costs, and biosimilars may circumvent patents because they are not the same as the original drugs. Consumer-interest organizations contend that a 12-year "government-issued monopoly" is "simply cruel" when applied to developing countries through a Trans-Pacific free trade agreement, because it will keep health care costs high. *See Pharmalot.com*, May 2, 2011.

FTC Proposes Ways to Prevent Patent Hold-Up in Collaborative Standards

The Federal Trade Commission (FTC) will conduct a **public workshop** on June 21, 2011, to present options aimed at preventing competition issues raised when patented technologies are incorporated in the standards developed by private, collaborative standard-setting organizations. Comments are requested by July 8, 2011.

According to FTC, "When industry-wide standards incorporate technologies that are protected by intellectual property rights, they raise the potential for 'hold-up' by a patent owner—a demand for higher royalties or other more costly or burdensome licensing terms after the standard is implemented than could have been obtained before the standard was chosen. Hold-up can subvert the competitive process of choosing among technologies during standard-setting and can undermine the integrity of those activities. Consumers can be harmed if manufacturers are able to pass on higher costs resulting from hold-up." While voluntary standards do not have the force of law, they are often adopted by governmental agencies under laws requiring them to rely on voluntary industry standards when developing new regulations.

During the workshop, FTC will explore three ways of preventing hold-up: through patent disclosure rules for standard-setting organizations, patent-holder commitments to license those using the standard under reasonable and non-discriminatory terms, and a requirement that patent holders disclose their licensing terms before a standard is adopted. Workshop participants will also discuss "antitrust issues, as well as examine how other legal doctrines (such as contract, patent, and consumer protection law), and economic and practical considerations affect the analysis of the issues."

LITIGATION

Federal Circuit Explores When Litigation Is "Reasonably Foreseeable" for Spoliation Purposes

The Federal Circuit Court of Appeals has issued rulings in companion patent-infringement cases involving the alleged spoliation of documents; at issue was a determination as to when litigation is "reasonably foreseeable," thus triggering a document-preservation duty. ***Micron Tech., Inc. v. Rambus Inc.,*** **No. 2009-1263 (Fed. Cir., decided May 13, 2011)**; ***Hynix Semiconductor Inc. v. Rambus Inc.,*** **Nos. 2009-1299, -1347 (Fed. Cir., decided May 13, 2011)**.

In *Micron*, a federal district court in Delaware determined that the 12 patents Rambus asserted against Micron Technology were unenforceable due to Rambus's spoliation of documents. In *Hynix*, a federal district court in California found that Hynix Semiconductor had infringed a number of valid Rambus patents and ordered Hynix to pay a $349 million judgment and prejudgment interest, and set a royalty rate for infringing products.

Rambus, which holds a group of patents relating to aspects of dynamic random access memory, apparently established a document retention policy under the guidance of a new vice president during summer 1998 and began destroying hundreds of boxes of documents in September of that year. Rambus ordered its outside patent counsel to purge his files of documents relating to the prosecution of the prospective patents in suit in April 1999. Rambus held a second "Shred Day" in August 1999, with an additional 300 boxes destroyed under the document retention policy. Rambus did not keep track of what was destroyed, but evidently admitted that some of the destroyed documents related, among other matters, to contract and licensing negotiations, patent prosecution, board meetings, and Rambus finances. The company filed its first infringement lawsuit in January 2000. Micron filed a declaratory judgment action against Rambus in August 2000, and Hynix filed similar litigation against Rambus the next day.

The Delaware court, which determined that Rambus had spoliated documents, found that litigation was "reasonably foreseeable to Rambus 'no later than December 1998, when [the new vice-president] had articulated a time

frame and a motive for implementation of the Rambus litigation strategy.'" According to the lower court, documents destroyed after December 1998 "were intentionally destroyed in bad faith," and thus, that the only reasonable sanction was to hold Rambus's patents in suit unenforceable against Micron. The California court presiding over Hynix's dispute determined that "litigation did not become reasonably foreseeable until late 1999, before which 'the path to litigation was neither clear nor immediate' and was subject to 'several contingencies [that] had to occur before Rambus would engage in litigation.'"

Rambus argued that "to be reasonably foreseeable, litigation must be 'imminent,' at least in the sense that it is probable and free of significant contingencies." Hynix argued that reasonable foreseeability does not incorporate an imminence of litigation requirement. Refusing to adopt Rambus's interpretation, the Federal Circuit noted that the standard is an objective, fact-specific one that requires the exercise of discretion "to confront the myriad factual situations inherent in the spoliation inquiry." While the standard does not trigger a duty to preserve documents "from the mere existence of a potential claim or the distant possibility of litigation," it does ask "whether a reasonable party in the same factual circumstances would have reasonably foreseen litigation."

Under this formulation of the standard, "[c]ontingencies whose resolutions are reasonably foreseeable do not foreclose a conclusion that litigation is reasonably foreseeable. It would be inequitable to allow a party to destroy documents it expects will be relevant in an expected future litigation, solely because contingencies exist, where the party destroying documents fully expects those contingencies to be resolved." According to the Federal Circuit, "[a]pplying the correct standard of reasonable foreseeability, without the immediacy gloss, these considerations compel a finding that litigation was reasonably foreseeable prior to Rambus's Second Shred Day."

The court affirmed the district court's determination in *Micron* that Rambus spoliated documents but vacated the dismissal sanction and remanded for further consideration. In *Hynix*, the court vacated the lower court's spoliation findings and remanded for reconsideration under the *Micron* framework.

Court Dismisses Action to Correct Inventorship of Two Patents

A federal court in Massachusetts has determined that genetic researchers could neither substitute themselves as the inventors of two patents nor correct the patents' inventorship to add their names under 35 U.S.C. § 256, because they had not engaged in any collaborative efforts with the named inventors. *Rubin v. The Gen. Hosp. Corp.*, No. 09-10040 (U.S. Dist. Ct., D. Mass, decided April 28, 2011). While the court granted the defendants' motion for summary judgment, it indicated that the plaintiffs might be able to establish priority of invention by initiating interference proceedings under 35 U.S.C. § 135.

The patents at issue involved inventions related to the discovery of two genetic mutations associated with Familial Dysautonomia (FD), an autosomal recessive disorder that primarily affects the Ashkenazi Jewish population. Half of those afflicted die by age 30. Identifying the mutations allows for the detection of potential carriers at risk of passing the trait to their children, and knowledge about the gene could facilitate the development of effective therapeutic approaches.

The plaintiffs are principal investigators in the FD field; they claimed that they discovered the gene mutations responsible for FD and prepared an article about their findings for publication, directing the publisher not to allow the defendant hospital's scientists to review it. The plaintiffs knew that the hospital's scientists were also working in the FD field, but the plaintiffs never worked in any way with the hospital's scientists. The plaintiffs claimed that these scientists read an abstract of the article and used the information to file a patent application on January 6, 2001. Thereafter, the plaintiffs filed their own provisional patent application, but the U.S. Patent & Trademark Office issued the FD-related patents in 2008 to the defendant scientists.

The court explains at some length how the patent law provision under which the plaintiffs proceeded does not provide the relief they requested. Section 256 allows a court to add named inventors or substitute named inventors to issued patents where a mistake in inventorship has been made. To be joint inventors, however, "there must be some element of joint behavior such as collaboration or working under common direction." The researchers here were not, according to the court, collaborators. Because no "rational trier of fact could conclude that Plaintiffs have proven that they are co-inventors of the patents at issue," the court ruled that the defendants were entitled to summary judgment. Nor could the plaintiffs be substituted as inventors because "section 256 is not intended to resolve disputes concerning priority of invention but is intended to encourage collaboration between and among inventors and correct the named inventors without the need to invalidate the patent."

NEWS BYTES

The U.S. Patent & Trademark Office (USPTO) has **expanded** its Enhanced First Action Interview Pilot Program to include all utility applications in all technology areas and filing dates. Under the program, which will run through May 16, 2012, applicants are entitled to a first action interview, upon request, before the first USPTO action on the merits.

The California Institute for Regenerative Medicine **issues** a proposed rule clarifying conditions for awarding stem-cell research grants. Comments are requested by May 23, 2011.

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The Food and Drug Administration announces the availability of industry guidance intended to help abbreviated new drug application (ANDA) applicants comply with final rule requirements for submitting bioequivalence data.

The National Institutes of Health (NIH) issues a notice of final actions under the *NIH Guidelines* for research involving recombinant DNA molecules.

UPCOMING CONFERENCES AND SEMINARS

The Biotechnology Industry Organization's 2011 International Conference is scheduled for June 27-30 in Washington, D.C. More than 15,000 are expected to participate in the event, which will include an exhibition, business forum and biotechnology program sessions. ■

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