Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

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IP NEWS

Federal Circuit Panel Divides over Indirect Infringement Law

A split Federal Circuit Court of Appeals panel has determined that an accused inducer's good-faith belief in the invalidity of a patent may negate the requisite intent for induced infringement. ***Commil USA, LLC v. Cisco Sys., Inc.*, No. 2012-1042 (Fed. Cir., decided June 25, 2013)**. The court determined that while a federal district court properly granted a motion for a new trial limited to induced infringement and damages, it improperly instructed the jury on re-trial as to induced infringement, allowing the jury "to find induced infringement based on mere negligence where knowledge is required." A dissenting judge would have ruled that the "fact of infringement does not depend on whether the inducer's view of patent validity is held in good faith or bad faith."

At issue was a patent involving wireless communications. Accused infringer Cisco Systems was unable to prevail on claims of patent invalidity and was found liable for direct infringement during a 2010 jury trial. The jury awarded patent holder Commil $3.7 million in damages. During a second trial in 2011, limited to indirect infringement and damages, Commil again prevailed and was awarded $63.7 million in damages, $10.3 million in prejudgment interest and $17,738 in costs. On appeal, Cisco challenged the jury instruction on inducement and also claimed that the trial court erroneously precluded it from "presenting evidence of its good-faith belief of invalidity to show that it lacked the requisite intent to induce infringement of the asserted claims."

The Federal Circuit agreed, citing *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011), for the proposition that induced infringement "requires knowledge that the induced acts constitute patent infringement." The court also rejected its own precedent "to the extent our prior case law allowed the finding of induced infringement based on recklessness or negligence," as inconsistent with *Global-Tech*. Finding the lower court's error prejudicial, the court remanded the case for a third trial, limited to induced infringement and damages. While dissenting Judge Pauline Newman agreed that a partial retrial was within the district court's discretion and agreed with the remand, she rejected as "contrary

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to the principles of tort liability, codified in the inducement statute," the majority's view that a belief in invalidity can negate infringement, and she disputed *Global-Tech's* relevance.

Myriad Genetics Sues Diagnostics Company over BRCA1 and BRCA2 Testing

Just weeks after the U.S. Supreme Court determined that naturally occurring human genes are not patent eligible and thus found certain Myriad Genetics patent claims invalid, Myriad Genetics and other patent assignees filed patent infringement claims against Ambry Genetics Corp., alleging that the company's addition of BRCA1 and BRCA2 analyses to its clinical diagnostic and genomic services infringes a number of patents that were not apparently affected by the Supreme Court's ruling. *Univ. of Utah Research Found. v. Ambry Genetics Corp.*, No. 13-0640 (U.S. Dist. Ct., D. Utah, Cent. Div., filed July 9, 2013).

Details about *Association for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398 (U.S. 6/13/13), appear in Issue 59 of this *Bulletin*.

The plaintiffs seek temporary and permanent injunctive relief to bar Ambry from infringing the patents, damages no less than a reasonable royalty, the destruction of infringing products, an accounting, attorney's fees, costs, and interest.

According to a press report, it had been unclear whether Myriad would seek to enforce the claims in patents underlying its BRACAnalysis®, although the company emphasized after the Supreme Court ruling that it still had 500 valid and enforceable claims. Several companies, including Ambry, announced that they would begin testing for BRCA alterations, and Ambry has apparently always included BRCA1 and BRCA2 on its cancer panels but did not perform analysis or reporting until after the ruling issued. Myriad has reportedly held a monopoly on the commercial BRCA testing market for 20 years; each analysis costs some $4,000. It alleges in its complaint against Ambry that it has invested more than $500 million to implement its discovery "and create a molecular diagnostic test for hereditary breast and ovarian cancer related to the BRCA1 and BRCA2 genes." *GenomeWeb.com*, July 10, 2013.

INVESTOR NEWS

Veracyte Secures $28-Million Series C Financing for Non-Invasive Thyroid Cancer Test

Veracyte, Inc., a South San Francisco-based firm that focuses on molecular cytology, has completed a $28-million Series C financing round to support the expansion and rollout of the company's first product, Afirma® Thyroid

FNA Analysis, a thyroid nodule test, which is evidently the only molecular test clinically validated to meet the criteria of National Comprehensive Cancer Network guidelines for safely monitoring thyroid nodules in lieu of invasive diagnostic surgery.

"We are pleased to have the support of GE Ventures, as well as of our current investors," said Co-Founder and CEO Bonnie Anderson. "This funding will help Veracyte expand availability of our Afirma Thyroid FNA Analysis to help more patients with inconclusive thyroid nodule fine needle aspiration (FNA) biopsy results potentially avoid unnecessary thyroid surgery." The financing included new investor GE Ventures, as well as existing investors Domain Associates, Kleiner Perkins Caufield & Byers, TPG Biotech, and Versant Ventures. *See Veracyte, Inc. News Release,* June 27, 2013.

Molecular Diagnostics Developer Raises $23.6 Million in Equity

MDxHealth, a molecular diagnostics company that develops epigenetic tests for cancer assessment and treatment announced that it has raised $23.6 million in a private placement by issuing 8.7 million new shares at €2.06 per share—the average closing price of the shares during the 30 preceding calendar days. The Liege, Belgium-based firm apparently plans to use the funds to "support and scale up" its U.S.-based commercial laboratory, U.S.-based sales and marketing efforts and commercial efforts for Clinical Molecular Diagnostics and Pharmaco Molecular Diagnostics solutions and services for clinicians and pharmaceutical customers.

"This financing marks a major milestone in the growth and success of our company, said MEDxHealth CEO Jan Groen. "In response to the increasing demand for our ConfirmMDx™ for Prostate Cancer test in the U.S., we will expand our commercial efforts by investing in personnel and infrastructure to ensure we are well positioned for new tests emerging from our product pipeline." *See MDxHealth News Release,* June 25, 2013.

Rutgers-Based Biorepository Receives $44.5 Million

According to a news source, the Rutgers University Cell and DNA Repository (RUCDR) has received a $44.5-million grant from the National Institute of Mental Health (NIMH) to fund RUCDR's NIMH Center for Collaborative Genomics on Mental Health Disorders, which provides services such as tissue sample collection, processing and advanced statistical and analytical consulting to NIMH investigators.

RUCDR provides DNA, RNA and cell lines with clinical data to hundreds of research laboratories around the world that use the information for studies on mental health and developmental disorders, drug and alcohol abuse, diabetes, and digestive, liver and kidney diseases. Some 85 percent

of the funds will apparently be used at RUCDR's Piscataway, New Jersey-based lab, and the remainder will be spent on support services from Washington University in St. Louis and the University of Southern California, which are part of the NIMH Center for Collaborative Genetic Studies on Mental Disorders. *See nj.com,* June 27, 2013.

BUSINESS CLIMATE

Biotech IPOs Continue Surge in Q2

According to news sources, global and domestic biotech companies have been raising capital at a blistering pace, with initial public offering (IPO) and investment activity soaring in the second quarter (Q2) of 2013. In the United States, 13 of the 21 IPOs were issued by life sciences companies, including 11 in the biotechnology sector and two in medical or health care. Venture-backed IPOs in Q2 doubled those in the first quarter. Meanwhile, global biotech companies reportedly raised $6 billion in Q2, a 20-percent increase over the $5 billion raised in the first quarter. The total for the year exceeds the same period in 2012 by 37.6 percent. *See Boston Business Journal*, July 1, 2013; *BioWorld Insight*, July 8, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Senate Committee Approves Bill Giving FDA Authority to Regulate Compounding Pharmacies

The U.S. Senate Committee on Health, Education, Labor, and Pensions has ordered that a proposed bill (**S.959**), which would amend the Food, Drug, and Cosmetic Act to give the U.S. Food and Drug Administration (FDA) authority over compounded drugs, be reported favorably, and it has been placed on the Senate's legislative calendar. Introduced by Sen. Tom Harkin (D-Iowa), the bill has drawn the concern of the natural health community, which has instituted a citizen campaign to oppose it. Advocacy organization Citizens for Health claims that the measure would give FDA the authority to "reduce or eliminate bioidentical hormone replacement therapy [and] stem cell research," and give the agency "broad and unprecedented power to regulate compounding pharmacy [sic]." *See Citizens for Health Action Alert*, June 25, 2013.

Bill Would Provide Federal Support for Human Stem Cell Research

U.S. Rep. Diana DeGette (D-Colo.) has introduced a bill (**H.R. 2433**) intended to "ensure a lasting framework for ethical embryonic stem cell research at the National Institutes for Health (NIH), and to bring certainty

to the scientific community pursuing research that could produce life-saving cures and treatments." In a statement, DeGette continued, "The United States has long served as the world leader in scientific and medical innovation, and it is critically important that we work together to make certain the breakthroughs of ethical embryonic stem cell research, and the jobs they create, happen right here at home." The Stem Cell Research Advancement Act of 2013, which has been referred to the House Committee on Energy and Commerce, would define which stem cells could be used in research, require the maintenance of guidelines for carrying out such research and prohibit funding for human cloning. *See Rep. Diana DeGette News Release*, June 19, 2013.

House Subcommittee Considers India's Pharmaceutical Patent Policies

During a recent hearing before the Subcommittee on Commerce, Manufacturing, and Trade of the House Energy & Commerce Committee, witnesses reportedly expressed concerns about India's intellectual property practices, particularly the revocation of pharmaceutical patents and the rejection of patent applications for drugs deemed insufficiently innovative. Among those testifying at the purported unfair trade practices hearing—"A Tangle of Trade Barriers: How India's Industrial Policy is Hurting U.S. Companies"—were representatives of the National Association of Manufacturers, U.S. Chamber of Commerce and drug makers.

According to one witness, "Since early 2012, India's policies and actions have undermined patent rights for at least nine innovative medicines. Many of these medicines have received patent protection in most countries across the world, suggesting that India is an outlier in recognizing and enforcing patent rights. This is not only increasing significant uncertainty in the market, but it also undermines our ability to compete fairly in India, and our willingness to invest there."

In a letter to U.S. lawmakers, however, India's Ambassador to the United States, Nirupama Rao, reportedly said, "India has a well-settled, stable, and robust intellectual property regime. In India, the IP framework is rooted in law." The country's commerce department also apparently opined to the U.S. Trade Representative that India's Patent Act "encourages genuine innovation by discouraging trivial, frivolous innovation, which leads to evergreening," a common practice whereby drug makers make small changes to a patented drug, enabling them to obtain a new patent and extend the term of patented exclusivity. India has evidently suggested that the U.S. government strengthen its patent laws to deter "undesirable practices." *See Energy & Commerce Committee Press Release*, June 27, 2013; *Corporate Counsel*, July 3, 2013.

FDA Signals Intent to Address Generic Drug Labeling Obligations

The U.S. Food and Drug Administration (FDA) has filed a notice with the Office of Management and Budget indicating its intent to initiate a rulemaking that would "revise and clarify procedures for changes to the labeling of an approved drug to reflect certain types of newly acquired information in advance of FDA's review of such change." According to FDA, the proposed revisions "would create parity" between brand-name and generic drug makers as to how they update their product labels.

Recent U.S. Supreme Court rulings have largely insulated generic drug makers from liability for state law-based inadequate labeling claims, because under current regulations they have no way to change their labels to reflect changes in understanding about potential risks. Rather, generic drug manufacturers must use the same label warnings as those provided by their brand-name counterparts.

An FDA spokesperson reportedly indicated that it would be "premature to cite what changes in the regulations might be," noting that FDA had indicated in the past that it would consider a rule change. Public Citizen Health Research Group senior adviser Sidney Wolfe welcomed the development, saying "It's common sense. It will obviously end this situation where people are being harmed physically and yet, although they are harmed, they have no right to go into court and get redress for serious damages." Public Citizen filed a petition with FDA in 2011 seeking parity in drug-labeling requirements. *See The New York Times*, July 3, 2013.

FDA Shuts Down More Than 1,600 Online Pharmacies Selling Counterfeit Drugs

International regulatory and law enforcement agencies, including the U.S. Food and Drug Administration (FDA), have seized nearly $41 million worth of illegal medicines from more than 9,600 Web sites worldwide in an effort dubbed Operation Pangea VI that ran from June 18-25, 2013. The action was part of the 6th annual International Internet Week of Action, a global cooperative effort among 99 countries to combat the online sale and distribution of potentially counterfeit and illegal medical products. FDA obtained seizure warrants for 1,677 of the Web sites and has posted on those sites a notice that the domain name has been seized because the sites were engaged in illegal activity.

According to FDA, many of the sites, described as "Canadian Pharmacies," appeared to be operating as part of an organized crime network that displayed fake medical licenses and certifications to convince customers that the medications they were purchasing were legitimate, brand-name products. Other sites reportedly used the names of popular pharmacies with domains such as "walgreens-store.com" and "c-v-s-pharmacy.com."

"Illegal online pharmacies put American consumers' health at risk by selling potentially dangerous products. This is an ongoing battle in the United States and abroad, and the FDA will continue its criminal law enforcement and regulatory efforts," said FDA Office of Criminal Investigations Director John Roth. "The agency is pleased to participate in Operation Pangea to protect consumers and strengthen relationships with international partners who join in this fight."

Described by FDA as "the largest Internet-based action of its kind in the United States," Operation Pangea targeted Web sites selling unapproved and potentially dangerous prescription medicines that FDA noted could pose significant public health risks. Products purchased from the Web sites also bypassed existing FDA safety controls. Medications sold included a diabetes and heart drug, a non-steroidal anti-inflammatory product, erectile dysfunction drugs, and a drug used to treat schizophrenia. *See FDA News Release,* June 27, 2013.

In a related development, the U.S. Government Accountability Office (GAO) has issued a **report** titled "Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad." The report details the complexities of rogue Internet pharmacies, which apparently consist of thousands of related Web sites run by operators that disguise their identities, and explains how they violate state and federal laws. GAO takes note of the collaborations between federal agencies and law enforcement abroad to disrupt these operations and of the steps FDA and others have taken "to educate consumers about the dangers of buying prescription drugs from rogue Internet pharmacies."

Draft Guidance Addresses Adverse Event Reporting Requirements for Medical Device Makers

The U.S. Food and Drug Administration (FDA) has issued draft **guidance** titled "Medical Device Reporting for Manufacturers." Comments are requested on the draft, which is neither final nor in effect, by October 7, 2013. According to FDA, the guidance "describes and explains the current FDA regulation that addresses reporting and recordkeeping requirements applicable to manufacturers of medical devices for certain device-related adverse events." Intended to update FDA policy and further clarify the agency's interpretations of regulatory requirements, the document will supersede 1988 and 1997 versions when finalized.

Among other matters, the draft document defines certain terms, including what constitutes a reportable event, who is considered to be a manufacturer, when awareness of a reportable event occurs, and what constitutes a serious injury or malfunction. *See Federal Register*, July 9, 2013.

GAO Report Finds Lack of Consensus on Value of Electronic Drug Labeling

The U.S. Government Accountability Office (GAO) has issued a **report** titled "Electronic Drug Labeling: No Consensus on the Advantages and Disadvantages of Its Exclusive Use." Based on a review of U.S. Food and Drug Administration guidance documents and regulations and interviews with federal officials and stakeholders, the report concluded that barriers remain to eliminating paper labeling entirely. While supporters of electronic labeling touted its advantages in terms of information currency and potential interactivity to enhance patients' knowledge about the drugs they use, others contended that too many may be uncomfortable using the medium or find it inconvenient or even unavailable. Some questioned whether multiple electronic sources of information would be reliable and unbiased.

CRS Releases Report on Security of Pharmaceutical Supply Chain

The U.S. Congressional Research Service (CRS) recently issued a report that provides a "background on pharmaceutical supply chain security and a discussion of policy considerations" against a backdrop of congressional efforts to adopt measures that would protect patients and manufacturers. Titled "Pharmaceutical Supply Chain Security," the report contains an overview of the types of interventions Congress is considering, including track and trace, standardized numerical identifiers, lot- or unit-based approaches, technology choices, interoperability requirements, data management and access, confidentiality, accountability, costs, and federal/state jurisdiction. CRS concludes that as the supply chain shifts to a global network of manufacturers, processers, packagers, importers, and distributors, it becomes more important to find a way to "keep counterfeit, mishandled and substandard drugs away from patients."

EU Adds Pharmaceuticals to Water Pollution Watch List

The European Commission (EC) has added 12 new substances to the European Union's (EU's) priority list of chemicals known to pose a risk to the safety of surface waters. In addition, for the first time, the EC has placed three pharmaceuticals—an anti-inflammatory painkiller and two hormone treatments—on a 'watch list' of emerging pollutants that the EC said could eventually be added to the priority list.

"Water policy is a long-term policy," commented Austrian Member of European Parliament Richard Seeber, who steered the legislation through the committee stages. "Our citizens should have access to clean water in every form … Unfortunately, studies show that we have some way to go to achieve good environmental status for chemicals, particularly in surface

waters." Commenting on the addition of drugs to the list, Seeber reportedly noted that this will be a "very interesting field in the future, because our waters are unfortunately increasingly burdened with pharmaceuticals."

The updated directive amends the 2000 Water Framework Directive, which governs how river, lake and coastal waters are monitored and how emissions into them are controlled across the EU. *See European Parliament News Release*, July 2, 2013; *PMLiVE.com,* July 8, 2013.

EU Trade Group Issues Voluntary Code for Disclosures by Pharma Companies

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has issued a "Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations" (**Disclosure Code**). According to EFPIA Director General Richard Bergström, "This is an important step for our industry, as we demonstrate our commitment to transparency and secure the trust of the patients our industry serves."

Adopted by the trade organization in late June 2013, the Disclosure Code will require member companies to disclose on their Web sites or a central platform (i) "The names of healthcare professionals and associations that have received payments or other transfers of value," and (ii) "The amounts or value transferred, and the type of relationship, such as consultancy fees, payment for travel or congress fees." The data will not become public until 2016 and will include information from 2015 forward only. Sanctions for code transgressions "should be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences. A combination of publication and fines will generally be considered to be the most effective sanction." *See EFPIA Press Release*, July 2, 2013.

LITIGATION

Second Circuit Rules Scientific Article Not Actionable Under Lanham Act

The Second Circuit Court of Appeals has determined that "to the extent a speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement, those statements are not grounds for a claim of false advertising under the Lanham Act." ***ONY, Inc. v. Cornerstone Therapeutics, Inc., No. 12-2414 (2d Cir., decided June 26, 2013)***. So ruling, the court upheld a lower court's dismissal of false advertising and tortious interference with prospective economic advantage claims filed against a competitor by

a company that makes surfactants for use in treating prematurely born infants with inadequate surfactant levels in their lungs.

The competitor had hired a company and several physicians to compile a database and present at medical conferences findings on "a study of the relative effectiveness of the different surfactants." The focus of the study was on mortality rate and length of hospital stay. The physicians subsequently published some of the findings in a peer-reviewed journal, and the competitor touted its conclusions and distributed promotional materials citing its findings.

Noting that statements of pure opinion are protected under the First Amendment, the Second Circuit discusses the difficulty of analyzing scientific findings for purposes of a false advertising complaint under the Lanham Act. According to the court, "the very premise of the scientific enterprise [is] that it engages with empirically verifiable facts about the universe. At the same time, however, it is the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision, because they represent inferences about the nature of reality based on the results of experimentation and observation." Because the plaintiff alleged "false advertising not because any of the data presented were incorrect but because the way they were presented and the conclusions drawn from them were allegedly misleading," and where "the authors readily disclosed the potential shortcomings of their methodology and their potential conflicts of interest," the court agreed with the lower court that the article's contents are not actionable.

Compounding Pharmacy Enters Consent Decree with FDA

As part of its efforts to ensure the safety of compounded pharmaceuticals since a Hepatitis A outbreak was traced in 2012 to a drug compounding facility in New England, the U.S. Food and Drug Administration (FDA) sought and obtained a permanent injunction against Med Prep Consulting, Inc. after an investigation revealed the presence of mold in some of its sterile drug products which were manufactured for some 70 hospitals and health care facilities. *United States v. Med Prep Consulting, Inc.*, No. 13-3856 (U.S. Dist. Ct., D.N.J., filed June 21, 2013).

FDA's complaint alleged that its inspection revealed insanitary conditions at the company's New Jersey facility and "numerous violations of current good manufacturing practice requirements for drugs." FDA also apparently found mold in injectable drug products and products that did not include sufficient active ingredients. The agency further contended that the company "produced and distributed numerous drug products without receiving patient-specific prescriptions and without having an approved new drug application or approved abbreviated new drug

application." According to FDA, the court entered a consent decree of permanent injunction against the company and its president and owner. Under the agreement Med Prep cannot manufacture, hold and distribute drug products until it complies with the law. In March 2013, the company voluntarily recalled all of its sterile products after it received notice from a customer that "floating particles were observed in a magnesium sulfate injectable drug product that was labeled as sterile." *See FDA News Release*, June 28, 2013

NEWS BYTES

The White House **issues** its "2013 Joint Strategic Plan on Intellectual Property Enforcement." Among other things, the plan calls for an increased focus on the proliferation of counterfeit pharmaceuticals and medical devices and measures to strengthen intellectual property enforcement through international organizations.

The U.S. Patent and Trademark Office (USPTO) **seeks** comments under the Paperwork Reduction Act on the information required for service of process and to secure USPTO employee testimony and the production of documents in legal proceedings, as well as for filing claims against USPTO under the Federal Tort Claims Act. Rules for these and related legal processes are outlined in 37 C.F.R. Part 104. Comments and recommendations for the information collection are requested by August 2, 2013.

The U.S. Food and Drug Administration (FDA) **schedules** a July 12, 2013, public meeting for input on developing regulations that would implement Title VII of the Food and Drug Administration and Innovation Act as to "standards for the admission of imported drugs and commercial drug importers." FDA invites meeting participants to address "the types of information that importers should be required to provide under Title VII" and "information regarding registration requirements for commercial drug importers and good importer practices to be established under Title VII." Written comments are requested by August 12, 2013.

The U.S. Food and Drug Administration (FDA) **announces** the availability of draft guidance for industry titled "Expedited Programs for Serious Conditions—Drugs and Biologics." The guidance provides "information on FDA's policies and procedures related to expedited drug development and review programs" and applies to "new drugs to address unmet medical need in the treatment of serious or life-threatening conditions." Comments on the draft are requested by August 26, 2013.

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The U.S. Food and Drug Administration **announces** the availability of draft guidance titled "Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products." "The draft guidance document provides sponsors of Investigational New Drug Applications (INDs) for cellular therapy (CT) and gene therapy (GT) products (referred to collectively as CGT products) with recommendations to assist in designing early-phase clinical trials of CGT products." Comments on the draft are requested by November 22, 2013. ■

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