Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

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IP NEWS

Federal Circuit Says Certain Human Genes May Be Patented

In a ruling likely to be appealed to the U.S. Supreme Court, a divided Federal Circuit Court of Appeals panel has determined that genetic discoveries may, to a certain extent, be patented. ***The Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office (Myriad Genetics, Inc.)*, No. 2010-1406 (Fed. Cir., decided July 29, 2011)**. The case involved a challenge to patent claims relating to "isolated gene sequences [composition claims] and diagnostic methods of identifying mutations in these sequences [method claims]." A district court had determined that isolated DNA molecules and methods of comparing molecules to determine whether a patient's genes have mutations that could cause breast and ovarian cancer could not be patented; the Federal Circuit reversed in part and affirmed in part.

According to Judge Alan Lourie, writing for the majority, one plaintiff had standing to bring the claims because Myriad Genetics, the patent holder, had sued him for patent infringement and he indicated that his lab would immediately begin again to perform genetic testing using the isolated DNA molecules at issue if the patents were invalidated. Explaining that "Myriad's claimed isolated DNAs exist in a distinctive chemical form—as distinctive chemical molecules—from DNAs in the human body, *i.e.*, native DNA," the court concluded that "the challenged claims are drawn to patentable subject matter because the claims cover molecules that are markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature." According to the court, isolated DNA "is a free-standing portion of a native DNA molecule, frequently a single gene. Isolated DNA has been cleaved (*i.e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule."

The appeals court agreed with the district court that most of Myriad's challenged method claims were patent-ineligible because they involved just one step of "comparing" or "analyzing" two gene sequences. Still, the court ruled that one method claim (20 of the'282 patent), involving "growing," "determining" and "comparing" steps, "claims patentable subject matter."

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A concurring judge joined the majority as to standing and the patentability of the method claims at issue, but wrote separately believing that "claims directed to isolated DNA sequences present a different set of issues." Judge Kimberly Moore focused on the law's distinction between "products of nature" and "human-made inventions," emphasizing the courts' flexible approach to the analysis. She meticulously distinguished between the different isolated DNA claims at issue, noting that the cDNA claims were based on sequences with "a distinctive name, character, and use, with markedly different chemical characteristics from either the naturally occurring RNA or any continuous DNA sequence found on the chromosomes."

According to Judge Moore, other DNA at issue, "shorter isolated DNA sequences," were patentable because they "have a variety of applications and uses in isolation that are new and distinct as compared to the sequence as it occurs in nature." "Longer strands of isolated DNA, in particular isolated strands which include most or all of the entire gene," Judge Moore observed, present a "much closer case." She concluded that these DNA molecules were patentable, but "for a reason different than for the shorter sequences." While they are different chemically, the longer isolated segments' "chemical and structural differences . . . do not clearly lead to an 'enlargement of the range of . . . utility' as compared to nature." Yet, Judge Moore would allow them patent protection for policy reasons, that is, Congress and the U.S. Patent and Trademark Office have allowed patents on isolated DNA sequences for decades, and the court should defer to them, as well as to "settled expectations."

Concurring and dissenting Judge William Bryson agreed with the court's judgments on standing, the patentability of the cDNA claims and the method claims, but disagreed as to "Myriad's BRCA gene claims and its claims to gene fragments." According to Judge Bryson, the question presented by the case was "whether an individual can obtain patent rights to a human gene." He concluded that the process of isolating genetic material from a human DNA molecule does not make the isolated genetic material a patentable invention. Noting that Myriad "was not the first to map a BRCA gene to its chromosomal location," Judge Bryson called "the discovery of the sequences . . . an unprotectable fact," although he would have allowed Myriad "to patent applications of its discovery." Because some of the company's "challenged composition claims effectively preempt any attempt to sequence the BRCA genes, including whole-genome sequencing," Judge Bryson would have found these claims unpatentable, "and a contrary ruling is likely to have substantial adverse effects on research and treatment in this important field."

Federal Circuit Upholds Fees, Costs and Sanctions in "Patent Troll" Litigation

The Federal Circuit Court of Appeals has determined that a district court correctly awarded litigation costs and attorney's fees to the defendant in an infringement action found to be an "exceptional case" and had sufficient

grounds to impose Rule 11 sanctions against the plaintiff, a company in the business of filing infringement actions to extract nuisance value settlements. *Eon-Net LP v. Flagstar Bancorp.*, No. 2009-1308 (Fed. Cir., decided July 29, 2011). So ruling, the court upheld an award of $631,000 to the defendant.

Among other matters, the court determined that the evidence supported findings that Eon-Net filed a baseless infringement action, destroyed relevant documents, failed to engage in the claim construction process in good faith, and displayed a lack of regard for the judicial system. According to the court, Eon-Net and its related entities had filed more than 100 similar lawsuits against a number of diverse defendants, when the district court made its exceptional case finding. "Each complaint was followed by a 'demand for a quick settlement at a price far lower than the cost of litigation, a demand to which most defendants have apparently agreed.'" At issue were patents for processing information from hard copy documents.

Senate Committee Approves Bill to End Pay-for-Delay Deals

The Senate Judiciary Committee has approved a bill (S. 27) that aims to "prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market." Called the "Preserve Access to Affordable Generics Act," the proposal would stop the practice of drug makers settling patent infringement claims with payments to generic manufacturers, a practice known as "pay for delay" deals.

While the bill has bipartisan support, it has previously died in the Senate and may not pass in the Republican-controlled House. It would give enforcement authority to the Federal Trade Commission and presume that an agreement settling a patent infringement claim in connection with the sale of a drug product has illegal anticompetitive effects, unless clear and convincing evidence shows that the "precompetitive benefits of the agreement outweigh" its anticompetitive effects. *See The Hill*, July 21, 2011.

NEW BIO BUSINESS VENTURES

Large-Scale Joint Drug Venture and MOUs Bind North Carolina and China's Zhejian Province

North Carolina's Hamner Institutes for Health Sciences and Ascletis Inc., a U.S.-China pharmaceutical company, have signed a memorandum of understanding (MOU) to support the first large-scale joint venture in biotechnology between North Carolina and China's Zhejian Province. Government officials also signed an MOU promoting economic growth, business development and trade, during the signing event. Ascletis has reportedly completed raising $100 million in Series A financing in 2011, which included a first tranche of $50 million.

According to press releases issued by both parties, Ascletis will establish its U.S. research and development center on Hamner's 56-acre campus in Research Triangle Park, while maintaining other operations in Zhejian. The company, which is working on new treatments for cancer and infectious diseases, will license the rights to late-stage experimental and commercial drugs for China.

"Being familiar with both the needs of the growing Chinese middle class and the promising drug candidates available for treatments in the United States, I knew that Ascletis needed a presence in both countries to succeed," Ascletis President and CEO Jinzi Wu was quoted as saying. "My goal is to ensure that Ascletis develops drugs that show potential for treating cancer, tuberculosis and other diseases into late-stage clinical trials and eventually out on the market to benefit society as a whole." *See Hamner* and *Ascletis Press Releases*, July 20, 2011; *AsianScientist*, July 24, 2011.

INVESTOR NEWS

Venture Capital Biotechnology Investments Increase 46 Percent in Second Quarter 2011

Venture capital funding of biotechnology companies has jumped 46 percent in 2011's second quarter, attracting $1.2 billion in 116 deals, according to a MoneyTree® Report released by PricewaterhouseCoopers LLC (PwC) and the National Venture Capital Association (NVCA). Medical device and equipment makers reportedly saw investments gain by 26 percent, raising $841 million in 90 deals.

According to a news source, the top three biotech deals reportedly involved Cameron Health Inc., a California-based medical device maker, which received $107 million; Virginia's Intrexon Corp., a synthetic biology company that garnered $100 million; and Massachusetts-based Merrimack Pharmaceuticals Inc., which received $77 million.

Ranking second behind the software industry, biotechs are evidently looking to replenish their portfolios after increases in acquisitions and initial public offerings (IPOs). "We continue to see acquisitions by major pharma and large biotech companies of smaller biotech companies, as well as the return of IPOs to the sector," venture capitalist Tracy Lefteroff was quoted as saying. "For funds that are fortunate to have those exits, that allows them to recycle money and put it into other deals." *See PwC/NVCA Press Release* and *Bloomberg*, July 20, 2011.

IPO Proposed by N.C.-Based Company Developing Experimental Medicines

North Carolina-based Argos Therapeutics has filed a Securities and Exchange Commission registration relating to its proposed initial public offering of common stock to raise more than $86 million to help pay for clinical tests of an experimental treatment for kidney cancer. The company apparently reported a $9.2 million loss in 2010; it has been funded to date by $89 million from private investors and more than $70 million in government grants. According to a press report, the company is also developing experimental medicines to treat HIV, lupus and other diseases based on technology involving white blood cells and the creation of personalized therapies. *See Argos Therapeutics News Release,* July 29, 2011; (Durham) *News Observer*, July 30, 2011.

Albuquerque Biotech Startup Announces $13 Million in Funding for Bacteria Diagnostics

nanoMR Inc., an early-stage life sciences company based in Albuquerque, New Mexico, has announced that it has raised $13 million in Series B venture capital to support commercializing a device that rapidly diagnoses bacteria in blood. Excel Venture Management reportedly led the round, joined by Healthcare Ventures, and existing investors, including vSpring Capital and Sun Mountain Capital.

Based on cooperative research by the University of New Mexico and an Albuquerque company specializing in magnetic resonance imaging, the device is being developed to allow bacteria detection in less than two hours, compared to 24-48 hours for typical laboratory tests, according to a news source. Tiny magnetic beads are reportedly attached to antibodies that embed themselves on potentially infected cells, which are processed through the device to monitor the beads' emissions.

"nanoMR is today demonstrating to the market that it is capable of detecting bacteria in minutes instead of days, with the potential of saving hundreds of thousands of lives in the process," vSpring Capital's managing director Dinesh Patel said. *See nanoMR Press Release* and *New Mexico Business Weekly*, July 19, 2011.

LEGISLATION AND REGULATORY DEVELOPMENTS

Lawmakers Introduce Legislation to Increase R&D Tax Credits

Bipartisan legislation has been introduced in the U.S. House of Representatives and the U.S. Senate (H.R. 2632, S. 1410) to encourage life sciences investment by increasing the existing research and development (R&D) tax credit.

The Life Sciences Jobs and Investment Act of 2011 would amend the Internal Revenue Code of 1986 to offer U.S. businesses tax incentives to hire additional researchers, make new investments in life sciences research and invest in new research facilities.

The legislation would reportedly allow companies engaged in life sciences to either double the R&D tax credit on the first $150 million invested (from 20 percent to 40 percent) or repatriate foreign earnings, when used exclusively for U.S. job creation and research, up to $150 million at a reduced tax rate of 5.25 percent. The tax breaks would be scheduled to end December 31, 2016.

"Life sciences are a key component of our economy," House bill sponsor Representative Devin Nunes (R-Calif.) said. "They support improved life-spans and a superior quality of life. We need to ensure America continues to lead in these important fields. One way to accomplish this is to reduce taxes on foreign earnings if those earnings are re-invested here in the United States." *See Rep. Devin Nunes Press Release*, July 25, 2011; *BNA Life Sciences Law & Industry Report*, July 29, 2011.

USPTO Proposes Rule to Revise Materiality Standard After *Therasense* Decision

The U.S. Patent and Trademark Office (USPTO) has **announced** its plan to "revise the standard for materiality for the duty to disclose information in patent applications and reexamination proceedings in light of the decision by the U.S. Court of Appeals for the Federal Circuit in *Therasense, Inc. v. Becton, Dickinson & Co.* Specifically, the Office is proposing to revise the materiality standard for the duty to disclose to match the materiality standard, as defined in *Therasense*, for the inequitable conduct doctrine." Comments are requested by September 19, 2011.

According to USPTO, this standard "should reduce the frequency with which applicants and practitioners are being charged with inequitable conduct, consequently reducing the incentive to submit information disclosure statements containing marginally relevant information and enabling applicants to be more forthcoming and helpful to the Office. At the same time, it should also continue to prevent fraud on the Office and other egregious forms of misconduct."

In *Therasense*, the court made it more difficult to challenge the validity of a patent by claiming that the applicant failed to disclose prior art to USPTO. The court adopted a "but-for-plus standard" as to the prior art's materiality, stating, "When an applicant fails to disclose prior art to the [USPTO], that prior art is but-for material if the [USPTO] would not have allowed a claim had it been aware of the undisclosed prior art." In other words, "In assessing the materiality of a withheld reference, the court must determine whether the [USPTO] would have allowed the claim if it had been aware of the undisclosed reference[,] . . . apply[ing] the preponderance of the evidence standard and

giv[ing] claims their broadest reasonable construction." The court excluded affirmative, egregious misconduct from the but-for materiality rule. *See Federal Register*, July 21, 2011.

IOM Deems 510(k) Medical-Device Clearance Process Flawed; FDA Seeks Comments

The Institute of Medicine (IOM) has issued a report titled "Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years," calling for an overhaul of Food and Drug Administration (FDA) procedures for approving medical devices that are considered a moderate risk to patients and are substantially equivalent to any previously cleared device or one that was on the market before the Medical Device Amendments were enacted in 1976. According to IOM, "Devices that were on the market before the Medical Device Amendments were never systematically assessed for safety and effectiveness—but they are being used as predicate devices." IOM also found that FDA's postmarketing surveillance of devices is insufficient.

Responding to concerns that the 510(k) premarket approval process for clearing medical devices may not ensure their safety and effectiveness and that the process has become cumbersome and time-consuming, IOM recommends that Congress change the medical-device regulatory framework. Specifically, IOM calls for the development of "an integrated premarket and post-market regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle." The framework would be (i) "based on sound science," (ii) "clear, predictable, straightforward, and fair," (iii) "self-sustaining and self-improving," and (iv) "risk based." The framework, according to IOM, would also "facilitate innovation . . . by making medical devices available in a timely manner."

Meanwhile, FDA has issued a request for comments on the report. Noting that the agency had requested the IOM review and report, FDA indicated that the agency had not yet fully evaluated it but recognized "the strong public interest in the comprehensive assessment of the 510(k) process and the IOM report." Comments must be submitted by September 30, 2011. According to an agency spokesperson, "FDA believes that the 510(k) process should not be eliminated but we are open to additional proposals and approaches for continued improvement of our device review programs." *See FDA News Release*, July 29, 2011; *Federal Register*, August 1, 2011.

FDA May Change Conflict-of-Interest Rules for Advisory Panel Members

Food and Drug Administration (FDA) Commissioner Margaret Hamburg has reportedly told an advocacy group that scientists with financial ties to drug and device-makers may soon be allowed to advise U.S. regulators about those products. Speaking recently to Public Citizen in Washington, D.C., Hamburg said a 2008 conflict-of-interest policy limiting researchers who were paid by

manufacturers from serving on FDA advisory panels is under review and may loosen by 2012. "We have to be sure FDA has subject-matter experts that we need for our important decision making," she reportedly said, adding that FDA must also "prevent inappropriate influence or distortion of information" that may result in compromised reviews.

Some lawmakers and manufacturers have reportedly criticized FDA for reviewing products too slowly because committees lacked enough qualified members. According to FDA, 23 percent of all seats on the agency's advisory committees went unfilled as of March 2011, with 608 positions occupied and 138 vacant. Among other changes also apparently under consideration would be the renewal of a law that allows the agency to receive fees from companies for product reviews, according to Hamburg. Public Citizen President Robert Weismann was quoted as saying that the rules should not be altered because financial ties influence how products are evaluated. "We need stronger protection rather than less," he said. *See Bloomberg*, July 25, 2011.

FDA Challenges Classification of Stem Cell-Based Bone Regeneration Product

The Food and Drug Administration (FDA) has **warned** Parcell Laboratories that it mischaracterized its stem cell-based bone regeneration product as a human cell, tissue and cellular or tissue-based product, when the product is actually a drug or a biologic and must conform to applicable regulations. According to a news source, Alphatec Spine has responded to FDA's warning letter on behalf of Parcell, providing more information about its existing classification.

FDA contends that the product "is dependent on the metabolic activity of living cells for its primary function and is not intended for autologous use or allogeneic use in a first or second degree blood relative." Alphatec Spine has responded with information about "how the product meets all of the criteria for being marketed under Section 361" (relating to human tissues or cells). The company's PureGen™ Osteoprogenitor Cell Allograft, under development with partner Parcell, is apparently used in spinal fusion procedures. *See Alphatec Spine News Release* and *Mass Device*, July 25, 2011.

LITIGATION

Court Dismisses Challenge to NIH Stem Cell Research Funding Guidelines

A federal district court in Washington, D.C., has dismissed a challenge to National Institutes of Health (NIH) guidelines on stem cell research funding. ***Sherley v. Sebelius*, No. 09-1575 (U.S. Dist. Ct., D.D.C., decided July 27, 2011)**. The court had previously granted a preliminary stay of the guidelines, after the D.C. Circuit Court of Appeals overturned its earlier ruling that the challengers lacked standing to pursue the litigation. The appeals court then

reversed the stay, finding that the plaintiffs were unlikely to prevail on the merits. Additional information about that decision appears in Issue 13 of this *Bulletin*.

The district court determined that the agency reasonably interpreted ambiguous federal law in developing the guidelines and that they were properly promulgated. The guidelines reflect a shift in White House stem cell policies occurring with the election of President Barack Obama (D) in 2008. His predecessor allowed federal funding of research involving embryonic stem cells, but only those that had been created before he addressed the nation about his policy on August 9, 2001. Current NIH guidelines allow federal funding of research using embryonic stem cells created since then, but not the research that derives the cells from human embryos, resulting in their destruction.

In its opinion, the district court notes that several of the legal issues the plaintiffs raised had been conclusively determined when the court of appeals considered whether the preliminary injunction was proper. Among them was whether the Dickey-Wicker Amendment, which Congress enacted to place restrictions on stem cell funding, was ambiguous and whether the courts were required to defer to NIH's interpretation of the amendment. Saying that it was bound by the "mandate rule" to obey appellate court rulings on issues of law, the court answered yes to both questions.

The court also found that NIH did not violate the Administrative Procedure Act by failing to respond to thousands of public comments calling for a wholesale ban on funding embryonic stem cell research. According to the court, the president's executive order "required the promulgation of Guidelines for funding embryonic stem cell research, and the NIH wasn't obligated to consider comments that, if adopted, would cause it to disobey the President and create an unlawful rule." Counsel for the plaintiffs has reportedly indicated that they are weighing whether to appeal the court's determination. *See Law360*, July 27, 2011.

NEWS BYTES

Marking the first time the U.S. Patent and Trademark Office (USPTO) has entered into an agreement with a provincial government, the USPTO announces a Memorandum of Understanding with the Jiangsu Provincial People's Government in the People's Republic of China. According to USPTO, activities contemplated under the agreement include improved enforcement and collaboration on "intellectual property matters, capacity building and other educational activities."

The National Biodefense Science Board of the Department of Health and Human Services announces a call for nominees for seven board memberships that are expiring December 31, 2011. Applications are requested by August

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19. The board advises the department on advances in biological and life sciences, biotechnology and genetic engineering vis-à-vis threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents.

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