Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

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Court Invalidates Many of Myriad's Gene Patents

In a stunning March 29 summary judgment ruling, Judge Robert W. Sweet of the U.S. District Court for the Southern District of New York invalidated some of the patents on the BRCA1 and BRCA2 genes granted to Myriad Genetics (Salt Lake City) and the University of Utah Research Foundation. The genes are associated with hereditary breast and ovarian cancer, and the patent holders claim the exclusive right to perform diagnostic testing on them and to license the testing to others. Myriad charges approximately $3,000 for its flagship BRACAnalysis test, which sequences a patient's BRCA1 and BRCA2 genes to detect mutations.

The ruling, which could ultimately affect gene patents generally, is the latest development in the lawsuit filed in May 2009 by the American Civil Liberties Union on behalf of patients, women's health groups, pathology groups, other medical organizations, and research centers *(Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.)*. Sweet released the U.S. Patent Office as a defendant in the lawsuit. He said that because he had already ruled in favor of the plaintiffs, it was unnecessary to address the ACLU's claim that human gene patents violate the First Amendment and are "products of nature" that cannot be privately owned.

Myriad Genetics will appeal the ruling to the Federal Circuit, a more patent-friendly court that some predict will curtail Sweet's broad attack on gene patents. Many legal experts foresee an appeal from the Federal Circuit to the Supreme Court. For more on gene patents, see *Inside the Diagnostics Industry*, p. 5.

PerkinElmer to Acquire Signature Genomics

PerkinElmer (Waltham, Mass.) has agreed to acquire Signature Genomic Laboratories (Spokane, Wash.). A filing with the Securities and Exchange Commission puts the purchase price at $90 million, which *DTTR* estimates is just over three times Signature's annual revenue. The transaction is expected to close by the end of May.

PerkinElmer described the acquisition as a way to strengthen its existing genetic testing service business and expand its position in early detection of disease, particularly in the area of cancer diagnostics. The company currently performs diagnostic testing through NTD Labs, which PerkinElmer acquired in July 2006. The Melville, N.Y.-based reference laboratory performs prenatal

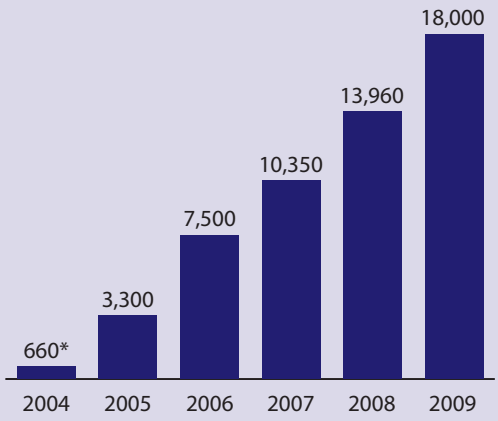
Continued on p. 2

▲ **PerkinElmer to Acquire Signature Genomics,** *from page 1*

screening for chromosomal abnormalities, maternal serum markers including alpha-fetoprotein, and carrier testing for cystic fibrosis.

"Signature brings very strong complementary assets for diagnosing disorders that are often undetected by traditional genetic tests," said Robert Friel, chairman and CEO of PerkinElmer.

Volume at Signature Genomics



*From April 2004

Source: Signature Genomics

Founded in 2003 by Lisa G. Shaffer, Ph.D., and Bassem A. Bejjani, M.D., as a partnership between Signature Genomic Services, Pathology Associates Medical Laboratories, and Sacred Heart Medical Center, Signature was the first laboratory to provide microarray-based cytogenetic testing. Today the lab offers full diagnostic cytogenetic services and interpretation with proprietary microarrays, flouresecent in situ hybridization (FISH) testing, and G-banded karyotype analysis. Signature's microarrays are offered for both prenatal and post-natal identification of DNA alterations associated with genetic disease. The company has approximately 120 employees and recently launched a suite of services for the diagnosis of patients with leukemia.

In a presentation at Washington G-2 Reports 2010 Molecular Diagnostics conference on April 15, Bejjani provided an in-depth look at Signature, which has pioneered a "genotype-first" approach to discovery and diagnosis with microarry-based cytogenetics. He cited the rapidly increasing test volumes, evolving technologies, and pressure on turnaround time as unique challenges to the business and highlighted potential for automation and digitization as unique opportunities.

ASCO and CAP Issue Joint Guideline for Hormone Receptor Testing in Breast Cancer

The American Society of Clinical Oncology (ASCO; Alexandria, Va.) and the College of American Pathology (CAP; Northfield, Ill.) have issued a joint guideline intended to improve the accuracy of immunohistochemistry (IHC) testing for the expression status of estrogen (ER) and progesterone receptors (PgR) in breast cancer. The recommendations are based upon a review of medical research literature, and they appear in the April 19 issues of the *Journal of Clinical Oncology* and the *Archives of Pathology & Laboratory Medicine.*

ER/PgR testing is to identify breast cancer patients with tumors whose growth is influenced by activation of the estrogen receptor pathway. As many as two-thirds of breast cancers are ER and/or PgR-positive, making these patients candidates for treatment with endocrine therapies such as tamoxifen and/or suppression of ovarian function. These treatments can substantially improve survival in patients with hormone receptor-positive invasive breast cancer.

Immunohistochemistry is used to determine the ER/PgR status of a tumor by measuring

protein amounts of ER and PgR in breast cancer cells. However, up to 10 percent to 20 percent of IHC test results throughout the world may be inaccurate (false-positive or false-negative), according to the systemic literature review undertaken by ASCO and Cancer Care Ontario. Most of the issues with testing have occurred because of variation in preanalytic variables, thresholds for positivity, and interpretation criteria.

Up to 20 percent of current immunohistrochemistry-based ER and PgR testing worldwide may be inaccurate (false-positive or false-negative).

The new guideline recommends that all newly diagnosed invasive breast cancers be tested for ER and PgR status and that repeat testing be performed in patients with recurring breast cancer. The focus of the guideline, however, is to establish "uniform testing measures that focus on proven, reliable, and reproducible assays and procedures." To that end, it recommends that laboratories that perform ER and PgR testing validate their assays against existing, clinically validated tests.

The guideline also details optimal tissue-handling requirements. It recommends transporting breast tissue specimens from the operating room to the pathology laboratory as soon as they are available for gross assessment. Additionally, the time from tumor removal to initiation of fixation should be kept to one hour or less, and formalin fixation should take between six hours and 72 hours.

According to the guideline, an ER and PgR test performed by IHC should be considered positive if at least 1 percent of the tumor in the sample tests positive, which helps predict whether a patient is likely to benefit with endocrine treatment.

Finally, ER and PgR testing should be performed in a CAP-accredited laboratory or in a laboratory that meets the accreditation requirements spelled out in the guideline. CAP will require that every accredited lab performing testing participate in a mandatory proficiency testing program.

"Increased attention to simple measures such as the handling of tissue specimens from the moment they are taken from the patient to when they reach the pathologist, the uniform fixation of specimens, the standardization and validation of lab assays, rigorous reporting procedures, and greater access to treatment interventions have the potential to significantly improve breast cancer outcomes around the world," said Elizabeth Hammond, M.D., co-chair of the ASCO/CAP Hormone Receptor Testing in Breast Cancer Panel and a pathologist at Intermountain Healthcare (Salt Lake City).

Classifying subtypes of breast cancer by a tumor's biological characteristics (tumor phenotype) can include whether or not it is hormone (estrogen or progesterone) receptor positive, human epidermal growth factor receptor 2 (HER2) positive, or "triple negative," lacking receptors for estrogen, progesterone, and HER2. In 2007, ASCO and the CAP issued clinical practice guideline recommendations to improve HER2 testing accuracy.

About 20 percent of all women with invasive breast cancer are HER2-positive, meaning they overexpress HER2, and about 15 percent of breast cancers do not express HER2, ER, or PgR receptors (triple-negative).

The ASCO-CAP panel chose to focus specifically on IHC assays for ER/PgR testing based on its widespread use, worldwide impact, and large body of evidence available. Future joint guidelines may address novel methods and predictive assays to identify patients most likely to benefit from endocrine therapies as new high-level data on validated assays and outcomes become available.

LabCorp Partners with Duke to Commercialize Biomarkers

LabCorp (Burlington, N.C.) and Duke University Medical Center (Durham, N.C.) are teaming up to commercialize biomarkers. The new joint venture, known as the Biomarker Factory, is designed to speed the translation of novel biomarkers into widely available clinical tools that can measure individual therapeutic responses, predict disease progression, and evaluate various biologic or disease-causing processes. Financial terms of the deal were not disclosed.

"The Biomarker Factory is at the intersection of translational medicine and personalized medicine," said Victor J. Dzau, M.D., Duke's chancellor for health affairs and CEO of Duke University Health System. "This joint venture will be uniquely positioned to accelerate the translation of scientific discoveries into clinical practice."

Among the biomarkers cited by the companies in their announcement of the joint venture were those that can assist clinicians in identifying which patients infected with hepatitis C virus (HCV) would respond best to treatment. In a study published last fall in *Nature*, a team led by Duke researchers John McHutchison and David Goldstein found that a genetic polymorphism near the IL28B gene is associated with an approximately twofold change in response to a widely used HCV treatment.

A key aspect of the collaboration will be working to integrate such findings into clinical decisionmaking. "We will be developing deep knowledge about appropriate use of biomarkers in clinical practice and how to provide this information so that patients and doctors can make better decisions," said Andrew Conrad, Ph.D., executive vice president and chief scientific officer of LabCorp.

The Biomarker Factory will make use of biological samples contributed by Duke, as well as the infrastructure already in place for a Duke-led, large-scale epidemiology study that is recruiting 50,000 people into a registry. The venture will also capitalize on a biorepository that LabCorp is developing to discover and validate biomarkers in human disease.

Both Duke and LabCorp have also recently signed deals with CancerGuide Diagnostics (Durham, N.C.), a startup company focused on molecular diagnostics for oncology. Led by LabCorp veterans Myla Lai-Goldman, M.D., and Bill Haas, CancerGuide is backed by a $10.5 million private equity financing agreement. LabCorp is among the four-year-old company's equity investors.

On April 5, CancerGuide announced that it had inked a research collaboration and licensing agreement with Duke to develop companion diagnostics for cancer therapies. The multiyear deal gives CancerGuide exclusive rights to a portfolio of published and well-validated molecular signatures that can predict individual response to targeted therapeutics. Earlier in the year, LabCorp signed on to help develop and commercialize CancerGuide's molecular oncology assays, which LabCorp subsidiary Esoterix will have exclusive commercial rights to use in conjunction with clinical trial pharmaceutical support services.

inside the diagnostics industry

Court Ruling Reignites Debate on Gene Patents

Even some staunch supporters of the diverse group of plaintiffs in *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, the lawsuit filed in May 2009 by the American Civil Liberties Union (ACLU) and the New York-based Public Patent Foundation, were doubtful of the case's chances of affecting the patentability of genes. Their skepticism was erased on March 29, when a federal district court judge invalidated many of Myriad Genetics' patents covering the BRCA1 and BRCA2 genes and their use in screening for elevated risk of breast and ovarian cancer.

In his surprise summary judgment ruling, Judge Robert W. Sweet of the Southern District of New York invalidated Myriad's patents on isolated DNA sequences to all or a portion of the BRCA1 and BRCA2 genes as well as its patent claims relating to analyzing or comparing isolated DNA sequences to detect mutations in a patient's BRCA1 or BRCA2 genes. "The identification of the BRCA1 and BRCA2 gene sequences is unquestionably a valuable scientific achievement for which Myriad deserves recognition, but that is not the same as concluding that it is something for which they are entitled to a patent," wrote Sweet in his 156-page opinion.

The ACLU hailed the decision, noting "it is the first time a court has found human gene patents unlawful and calls into question the validity of patents now held on approximately 2,000 human genes." These include genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, and spinocerebellar ataxia.

The ACLU holds that Myriad's monopoly on BRCA testing makes it impossible for women to access alternate tests or to get a comprehensive second opinion about their mutation status. The monopoly also allows Myriad to charge a high price for testing, the plaintiffs said. In Europe, where Myriad's patent rights were severely limited by European Union courts in 2004, BRCA testing is available for approximately $1,900, compared to the $3,150 currently charged by Myriad.

Myriad and its supporters stand behind gene patents as critical to attracting private investment and stimulating research. They also dispute the allegation that gene patents impede access to diagnostic testing or increase test prices. In an amicus brief filed last December in support of Myriad, the Biotechnology Industry Organization cited a report of the U.S. Secretary of Health and Human Services Advisory Committee on Genetics, Health, and Society that found pricing between patented genetic tests, including Myriad's BRACAnalysis, to be comparable to equivalent nonproprietary genetic tests.

As potential competitors for BRCA testing are expected to await the outcome of Myriad's appeal to the Federal Circuit, it is important to note that Myriad's early BRCA1 and BRCA2 patents are unusually broad and disease-specific. Few other companies have built business models similar to that of Myriad, which has cornered the market in testing for familial breast and ovarian cancer.

A study by researchers at the University of Leuven in Belgium that was published in *Nature Biotechnology* in 2009 examined the patent landscape for 22 of the most frequently tested inherited diseases. While a quarter of the identified patents claimed a human gene (as opposed to primers or probes, genetic diagnostic methods, or diagnostic kits), only 3 percent of the gene claims were classified as blocking. Given the absence of a discernible "patent thicket," the researchers suggested that rather than focus on banning gene patents, "More attention should be paid to the licensing practices in a responsible way."

For Heart Transplant Patients, Molecular Testing Can Offer Alternative to Biopsies

The results of a multicenter clinical trial indicate that AlloMap, a noninvasive molecular diagnostic test that helps physicians identify patients with a low probability of heart transplant rejection, is just as good as routine biopsies for monitoring post-transplant patients. The study results were presented on April 22 at the 2010 meeting of the International Society for Heart and Lung Transplantation in Chicago and published online in the *New England Journal of Medicine* in advance of publication in the journal's June 17 print edition.

Developed, marketed, and performed exclusively by XDx (Brisbane, Calif.), AlloMap is a multigene in vitro diagnostic multivariate index assay (IVDMIA) that assesses the gene expression profile of RNA isolated from peripheral blood mononuclear cells. The test is offered by 65 transplant centers in the United States and its price of approximately $3,000 is reimbursed by many insurers.

Commercially available since 2005, AlloMap was cleared by the U.S. Food and Drug Administration (FDA) in 2008 to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of acute cellular rejection at the time of testing. Although AlloMap is used to monitor transplant recipients for rejection, it had never been compared systematically in clinical practice with the current standard approach to monitoring for rejection with the use of routine biopsies.

The recent study, known as the Invasive Monitoring Attenuation through Gene Expression (IMAGE) clinical trial, randomly assigned 602 patients who had undergone heart transplantation to be monitored for rejection using AlloMap or routine endomyocardial biopsies, in addition to clinical and echocardiographic assessment of graft function. They then compared the approaches with respect to clinical outcomes.

"We found that patients undergoing rejection monitoring using [AlloMap] underwent significantly fewer biopsies and were more satisfied with the biopsy-minimization approach compared to patients who underwent routine biopsies at regular intervals," said Michael Pham, M.D., M.P.H., the study's co-lead investigator and a transplant cardiologist at the Stanford University Medical Center. "Patients in both groups experienced similar rates of clinically apparent rejection, cardiac dysfunction, death, or the need for a second transplant."

"Our study suggests that gene-expression profiling of peripheral-blood specimens may offer a reasonable alternative to routine biopsies, for monitoring cardiac-transplant recipients for rejection if the interval since transplantation is at least 6 months and the patient is considered to be at low risk for rejection," conclude the authors in the *NEJM.* "However, the study had limited power to allow for a firm conclusion to be reached regarding the use of gene-expression profiling as a substitute for the performance of biopsies." Resolving this issue would require a larger trial with a longer follow-up period.

XDx has submitted the results of the IMAGE trial to the FDA for a label extension for AlloMap compared with biopsy.

Cleveland HeartLab Looks to Grow Advanced Lipid Testing

Following its launch in November 2009, Cleveland HeartLab recently completed a $3 million funding round, which will be used to advance sales and marketing efforts for its advanced lipid testing services, as well as expand its CLIA lab operations.

Located on the main campus of the Cleveland Clinic, the specialty clinical laboratory and disease-management company performs biomarker-based testing to assess a patient's risk of inflammation in cardiovascular disease. In fact, approximately 50 percent of people who have a cardiac event such as a heart attack or stroke have normal lipids, according to Cleveland HeartLab's President and CEO Jake Orville. "Although advanced lipid testing is certainly a better method to assess risk beyond normal lipids, vascular inflammation is what causes the event," he added.

While the Cleveland HeartLab offers a comprehensive menu of cardiovascular risk profile testing services, the company's proprietary offering is the CardioMPO. This Food and Drug Administration-cleared test is based on technology discovered and developed at the Cleveland Clinic. CardioMPO is an enzyme immunoassay that assesses the amount of myeloperoxidase, or MPO, in human plasma. MPO levels are linked to both inflammation and oxidative stress.

"Our company was founded to take valuable research and intellectual properties founded at the clinic to commercialization," said Orville. "We are already receiving hundreds of samples weekly from across the country from physicians interested in more specific cardiovascular risk assessment related to inflammation."

The HeartLab's current four-person commercial team is focused on selling to community-based lipid physicians, also known as lipidologists. "These are practitioners seeing patients 55 and older that have a risk factor, whether it's family history, high blood pressure, or other factors that indicate they should be screened for risk of heart disease," said Orville.

This recent capital infusion will go toward expanding the sales staff to a total of five or six this year. A broader sales effort will allow the HeartLab to go deeper into the lipid and advanced lipid testing markets. The lipid testing market comprises about 64 million tests annual (nonhospital) volume and is valued at approximately $1.8 billion, according to Orville, who estimates that the advanced lipid testing market could reach an annual value of approximately $5 billion.

Radient Pharmaceuticals Expands Commercialization of FDP Test

Radient Pharmaceuticals (Tustin, Calif.), the company formerly known as AMDL, is looking to boost sales of its Onko-Sure test by selling kits to CLIA laboratories and through new corporate partnerships. Radient began marketing the immunoassay through third-party in vitro diagnostics distributors in early 2009 and last year earned approximately $1.1 million in revenue on kit sales.

Onko-Sure is a quantitative enzyme-linked immunosorbent assay that measures fibrin and fibrinogen degradation products (FDP) in human serum. Levels of FDP rise substantially as cancer progresses.

In July 2008, the U.S. Food and Drug Administration cleared the Onko-Sure test for use in monitoring the disease progression of patients who have previously been diagnosed with colon cancer. Outside of the United States, the test has received regulatory approval for use in the detection and monitoring of lung cancer and as a general cancer screen.

Radient forecasts that CLIA laboratories will perform as many as 200,000 Onko-Sure tests in 2010. The company projects 2010 sales of the high-margin kits to reach $17.2 million, which would translate into $13.4 million in earnings.

Clinical Trial for Lung Cancer Demonstrates Value of Molecular Testing

An innovative clinical trial offers an encouraging model for integrating molecular testing into cancer treatment, according to a presentation on April 19 at the annual meeting of the American Association for Cancer Research. Researchers at the University of Texas M. D. Anderson Cancer Center presented the results of the study, which used a statistical model to match four drugs to specific biomarkers in the tumors of 255 stage IV non-small cell lung cancer patients who had received between one and nine previous treatments.

"New drugs that target molecular pathways help a small percentage of lung cancer patients, but right now there's no way to determine who those patients are before treatment," said Edward Kim, M.D., an associate professor at M. D. Anderson and principal investigator on the Biomarker-Integrated Approaches of Targeted Therapy for Lung Cancer Elimination (BATTLE) clinical trials.

BATTLE may also lead to more precise clinical trials that will require smaller numbers of patients to test a targeted therapy rather than large trials open to all comers. "Lung cancer research has been plagued by large, Phase III clinical trials that showed minor effects or even failed to enroll enough patients to finish," Kim said.

The Phase II clinical trial found evidence that each of the four drugs targets specific molecular signatures better than the other three. The drugs used in the trial were erlotinib (Tarceva), sorafenib (Nexavar), vandetanib (Zactima), and erlotinib with bexarotene. Each drug is designed to target specific molecular pathways; currently, none has a validated biomarker to guide its use.

BATTLE's end point was disease control at eight weeks, which recent research has found is a good indicator of overall survival. Overall, 46 percent of patients on the trial had disease control at eight weeks, compared with a historical experience of around 30 percent for late-stage lung cancer patients. Median overall survival was nine months, and 38 percent of patients survived to one year.

Kim cautioned that Phase II trial findings of biomarker effectiveness need to be validated in Phase III trials, which are typically sponsored by pharmaceutical companies or performed in cooperative groups.

"BATTLE is an important step toward personalized medicine and marks a paradigm shift for clinical trials by demonstrating the feasibility of a biopsy-based, hypothesis-driven biomarker trial," said Roy Herbst, M.D., Ph.D., co-principal investigator on the BATTLE clinical trials.

Patients agreed to have a new biopsy for the trial, Kim said, which was crucial to the study design because it provided fresh information on the tumor's molecular status that may have been altered by treatment since the patient's previous biopsy.

Future BATTLE trials will test combinations of therapies as well as single agents and will concentrate on the entire range of staging for lung cancer patients, including front-line therapy. Ultimately, the researchers plan to try the BATTLE approach in personalizing prevention clinical trials.

Genetic Test Could Identify Best Candidates for Statins

A genetic test can help determine in which patients cholesterol-lowering statin drugs might have the most benefit in also reducing the risk of colorectal cancer. According to a study slated to appear in the May 1 issue of *Cancer Prevention Research*, a genetic variant affects how statins control both colorectal cancer and cardiovascular disease risk.

Previous research has shown that statins—which 25 million people worldwide take each day to reduce their risk of cardiovascular disease—can cut risk of colorectal cancer by 50 percent. However, the effectiveness of statins varies widely among patients.

"Our research is the first step towards personalized prevention. Some people benefit substantially more from statins than others—for both cholesterol lowering and colorectal cancer prevention," said senior study author Stephen Gruber, M.D., Ph.D., M.P.H., director of cancer prevention and control at the University of Michigan Comprehensive Cancer Center. "Now we have identified a genetic test that can show who's likely to benefit most from this drug."

The researchers looked at 2,138 people in Northern Israel who were diagnosed with colon cancer and 2,049 similar people without colon cancer. All participants were asked about statin use for controlling cholesterol. Statins are not currently used to prevent colorectal cancer.

In addition, the researchers took blood samples from all study participants and measured single nucleotide polymorphisms in 40 genes. They found that the gene targeted by statins, HMGCR, is the same gene that predicts the drug's benefit for preventing colorectal cancer. Further, there are two versions of HMGCR—a long version and a short version. The researchers found that statins have more benefit for reducing both colorectal cancer risk and cholesterol in the gene's long version.

"It's the exact same mechanism for lowering cholesterol as it is for lowering colon cancer risk," said Gruber. "This is true only for those people who are actually taking statins. The gene test by itself doesn't predict whether you're at an increased risk of colon cancer; it predicts only how well statins lower the risk."

The researchers point out that it's easy to know if statins are successfully lowering cholesterol, but their effect on colorectal cancer prevention is not as apparent. That's where a gene test would come in.

"We think we understand the reasons why statins lower the risk of colorectal cancer," added Gruber. "It's probably related to the fact that in addition to lowering cholesterol, they also decrease inflammation—and we know inflammation is a very important part of the way in which colon cancers develop. But regardless of whether it's related to cholesterol levels itself or inflammation, it's more important to know who are the right people to use these drugs for."

In an accompanying editorial, John A. Baron, M.D., a professor at Dartmouth Medical School, was not optimistic that variations in HMGCR genotype could explain the somewhat inconsistent association of statins with risk of colorectal cancer, although he was enthusiastic about the diagnostic implications of the study. "It seems unlikely that variation in HMGCR explains variation in the reported findings on statins and colorectal cancer," he noted. "But it is intriguing that this pharmacogenomics study could lead to the identification of individuals among whom statins decrease risk."

Medicare Physician Fee Cut Blocked Through May

On April 15, President Obama signed legislation (H.R. 4851) delaying a 21 percent Medicare payment cut for physicians through May 31. The cancellation of the cut is retroactive to April 1. Medicare physician fees have been frozen at their 2009 levels since the start of this year, while Congress grapples with reform of the Sustainable Growth Rate (SGR) formula, which required the 21 percent cut.

In response, the Centers for Medicare and Medicaid Services announced that claims with dates of service April 1 and later that were being held by Medicare contractors are being released for processing and payment. The statutory payment floors still apply and, therefore, clean electronic claims cannot be paid before 14 calendar days after the date they are received by contractors (29 calendar days for clean paper claims).

The extension law also contains a provision that permits certain hospital-based physicians to be eligible for health information technology incentives for "meaningful use," as authorized by the American Recovery and Reinvestment Act.

It also extends eligibility for a 65 percent subsidy for health care coverage under the Consolidated Omnibus Budget Reconciliation Act.

The American Medical Association (AMA) is urging Congress to pass a permanent fix to the Medicare physician payment system. "Repeated delays and continued uncertainty combined with the fact that Medicare payments, even without the 21 percent cut, have not kept up with the cost of providing care to seniors demonstrates the need for a permanent solution to this annual problem," AMA said in an April 16 statement.

IVD Stocks Gain 2%; Nanosphere Climbs 49%

The G-2 Diagnostic Stock Index gained an average of 2 percent in the five weeks ending April 16, with 11 stocks up in price and seven down. The G-2 index is up by 8 percent since January, while the Nasdaq has gained 7 percent and the S&P is up 4 percent over the same period.

The biggest gainer in past weeks was **Nanosphere** (Northbrook, Ill.), which climbed 49 percent to close at $5.02 per share and a market capitalization of $170 million. The molecular diagnostics company recently announced that its respiratory virus panel performed on the bench-top Verigene SP instrument has been categorized by the U.S. Food and Drug Administration (FDA) as "moderate complexity" under CLIA. It is the first Nanosphere test to attain the designation, which allows the test to be run by a broader range of laboratories than those categorized as "high complexity." The company plans to file all of its previously cleared and future assays on its Verigene SP system in the hope that more tests will be categorized as "moderate complexity."

Meanwhile, another company focused on molecular diagnostics was the poorest performing stock. **Sequenom** (San Diego) plummeted 29 percent, ending the period with a share price of $5.80 and a market capitalization of $369 million. On April 7, an analyst at Wedbush Securities initiated coverage of the stock with an "underperform" rating and reservations about Sequenom's potential, citing the company's inconsistent track record and financing risk as well as increased competition in the genetic testing space.

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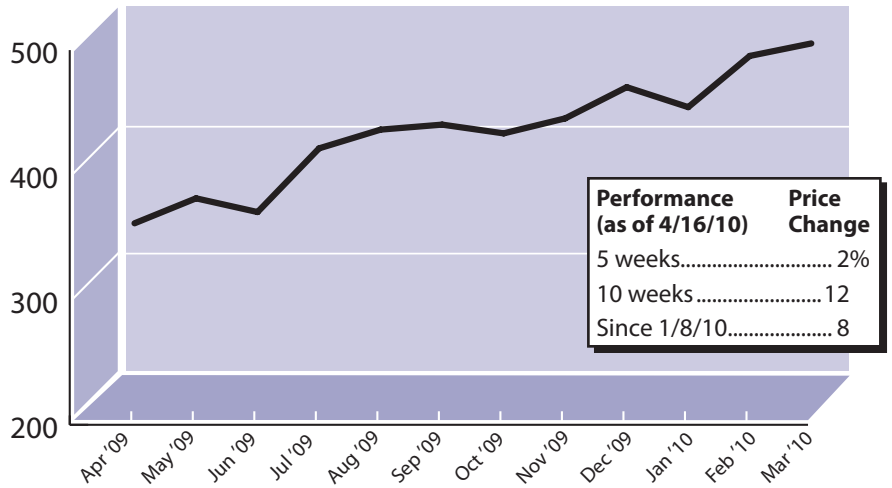
More recently, Sequenom launched its next-generation mass spectrometry system, the MassArray analyzer 4. The new bench-top instrument can perform quantitative gene expression analysis, epigenetic nucleic acid methylation analysis, as well as high-throughput genotyping and single nucleotide polymorphism fine mapping applications. The platform will initially be offered to research-use-only laboratories and, subject to FDA clearance, will be released to CLIA-certified laboratories for developing and performing laboratory-developed tests.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 18 IVD companies.

Up	Price	% Chg
Abaxis	$26.25	2%
Affymetrix	8.00	1
Bio-Rad	107.98	7
Cepheid	19.01	8
Gen-Probe	48.00	2
Immucor	21.54	2
Johnson & Johnson	65.02	2
Luminex	17.54	8
Nanosphere	5.02	49
OraSure	6.61	49
Quidel	14.81	7
Down		
Abbott Labs	$52.26	-3
Beckman Coulter	60.90	-13
Becton Dickinson	77.74	-1
Clinical Data	19.44	-5
Inverness Medical	38.50	-4
Meridian	19.27	-17
Sequenom	5.80	-29

G-2 Insider

Ready to optimize your outreach testing?... Don't miss Washington G-2 Reports' and Chi Solutions' annual Laboratory Outreach Conference, the premier business event dedicated to improving the performance, profitability, service, and value of hospital and health system laboratory outreach programs. This year's conference will take place June 2-4 at the Hyatt Regency Baltimore in Baltimore. Scheduled sessions include:

- A keynote address by Bud Thompson, executive vice president of Carilion Health System and CEO of Carilion Labs/Spectrum Laboratories, who will discuss the major value components and strategic benefits that outreach delivers to the laboratory and its parent organization;
- A keynote address by Don Toussaint, vice president of lab services at Legacy Laboratory Services, that will look to the future of laboratory outreach testing, including how innovative business models are driving revenue growth and market penetration;
- An in-depth look at how your laboratory can harness the power of informatics to improve technical and management processes as well as better serve clients from Walter H. Henricks, M.D., medical director of the Center for Pathology Informatics at Cleveland Clinic;
- Case studies of Catholic Medical Center, which recently demerged after a decade-long merger agreement with a national lab, and of Regional West Medical Center, has grown from a small hospital-based outreach program in rural Nebraska to a multimillion-dollar laboratory spanning five states.

For full program details or to register, visit www.g2reports.com/outreach10 or call Jeff Watkins at 800-401-5937 ext. 4709.

Company References

ASCO 571-483-1300

CancerGuide Diagnostics
919-474-2439

CAP 847-832-7000

Cleveland HeartLab
216-444-9886

CMS 410-786-3000

Duke University Health System
888-275-3853

Intermountain Healthcare
801-442-2000

LabCorp 800-526-3593

Myriad Genetics 801-584-3600

Nanosphere 888-837-4436

PerkinElmer 781-663-6900

Sequenom 858-202-9000

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