G2 Compliance Report

G2 INTELLIGENCE

For Hospitals, Laboratories and Physician Practices

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Inside this issue

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Illegal Marketing Practices at Issue in Two Lawsuits Involving Labs

Clinical laboratory Ameritox Ltd. April 9 sued competitor Millennium Laboratories Inc. in federal court in Florida, alleging that Millennium's nationwide marketing strategy for its urine drug testing practices violates the Lanham Act and state unfair competition laws (*Ameritox Ltd. v. Millennium Laboratories Inc.*, M.D. Fla., No. 8:11-CV-775).

In the complaint, filed in the U.S. District Court for the Middle District of Florida, Baltimore-based Ameritox claims that Millennium aggressively and deceptively promoted its services to health care providers nationwide, inducing physicians to use Millennium over other laboratories.

The complaint also alleges that Millennium offered illegal financial inducements to health care providers in violation of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and several state anti-kickback statutes, including those of Arizona, Florida, California, New Hampshire, and Texas.

Continued on page 2

Palmetto's MolDx Program Now in Effect; Labs Must Obtain Test Identifiers to Be Paid

Palmetto GBA's new Molecular Diagnostic Services Program (MolDx) is now in effect and all laboratories performing molecular diagnostic testing and billing in the J1 Region must now apply for a unique identifier for each assay in order to be paid.

The MolDx program became effective May 7 for all claims for molecular tests in Medicare's J1 Part B region, which covers California, Nevada, Hawaii, and the U.S. Pacific territories of Guam, American Samoa, and the Northern Mariana Islands. Under the program, Palmetto is requiring that all labs that perform molecular diagnostic testing and bill Medicare in the J1 region obtain either a McKesson Z-Code or a Palmetto Test Identifier (PTI) to identify each molecular diagnostic test for which it is seeking coverage and reimbursement. Applications are required for CPT codes 83890-83914, 88384-88386, and the "pathology/laboratory not otherwise classified" (NOC) codes. Certain tests are exempt (*see chart on p. 9*).

Labs are required to submit test information and supporting evidence for each test, which then will go through a technical assessment process in which subject matter experts from academia and industry will

Continued on page 9

Two Lawsuits Involving Labs, *from page 1*

Ameritox asked the court to enjoin Millennium's allegedly illegal practices. It also seeks to recover all profits Millennium derived from its allegedly illegal acts as well as treble damages, punitive and exemplary damages, and attorneys' fees.

Ameritox claims that Millennium's business model "effectively corrupts the health care provider's decision-making process by improperly introducing enormous financial incentives that mislead health care providers into believing that it is lawful for them to accept illegal inducements and that it is proper, and even compulsory, to order for each and every one of their patients . . . medically unnecessary confirmatory testing."

Response

Martin Price, San Diego-based Millennium's general counsel, says that the entire suit is "baseless" and "a pathetic waste of resources."

"It's becoming hard to track all the lawsuits Ameritox has filed," Price said. "Each week seems to bring a new lawsuit against someone or some company."

Price also said Ameritox's most recent complaint against it—which is its second attempt to amend its original complaint—is a "rehash of the same allegations" that a court largely had dismissed in 2011.

> ***"Health care providers are deceived into believing that Millennium's false and misleading offer to waive a patient's co-payment and/or deductible is legal and accurate and is one that health care providers can lawfully offer their patients."***
>
> ***—Ameritox***

Ameritox and Millennium directly compete for market share in the urine drug testing and medication monitoring market nationwide, including in Arizona, Florida, California, New Hampshire, Tennessee, and Texas. According to the complaint, Millennium designed its business model to "wrongfully disrupt Ameritox's business practices within the same market."

Ameritox alleges that Millennium's marketing strategy used national, centrally coordinated sales presentations, marketing materials, and commercial advertisements that misled providers into believing that they could properly implement Millennium's billing model and promised those same providers that they could earn hundreds of thousands of dollars annually.

Among other things, Ameritox alleges that Millennium sent billing letters to health care providers and patients containing false and/or misleading statements in violation of the Lanham Act, 15 U.S.C. § 1125.

Statement on Medicare Copays

One of Millennium's allegedly false and misleading statements in the billing letters included Millennium's claim to health care providers and their patients that Medicare patients will not be charged a deductible or copayment if Millennium processes the patient's laboratory results, the complaint said.

"By law, Medicare patients are not charged a deductible or co-payment for laboratory work. Florida Medicaid patients are likewise misled by the advertisements, as these patients are subject to a $1.00 co-payment. These advertisements mislead patients enrolled in a private insurance program as well because many private insurers include charges for laboratory services within a member's annual deductible," Ameritox said in the complaint.

In addition, Ameritox said, "Health care providers are deceived into believing that Millennium's false and misleading offer to waive a patient's co-payment and/or deductible is legal and accurate and is one that health care providers can lawfully offer their patients."

Other examples of Millennium's allegedly false or misleading statements include its representation that a fractional ownership billing arrangement it offered to providers complied with federal and state laws.

"Millennium's false or misleading statements have already, and will continue, to influence materially purchasing decisions to the extent that customers choose Millennium's services, based on the promise of unlawful and illusory benefits, instead of those offered by Ameritox," the complaint said.

Financial Inducements

In addition, Ameritox said Millennium illegally used financial incentives to increase its market share at the expense of Ameritox.

These incentives included the practice of illegally offering doctors financial incentives—such as providing doctors with point-of-care testing cups and supplies for free or at below-market rates—to induce them to order medically unnecessary tests from Millennium. Other incentives included offering, at a nominal cost, the services of a consultant to help health care providers obtain waivers of the Clinical Laboratory Improvement Amendments regulations, a process that generally is lengthy and costly.

In a separate, unrelated lawsuit, Millennium Laboratories Inc. April 16 accused a medical laboratory sales representative of offering doctors illegal kickbacks to induce them to use another medical laboratory to test patients' specimens.

The complaint also stated that "to induce Health Care Providers to use Millennium for their urine drug testing laboratory services, Millennium provided free advice on how to manipulate the coding system used to bill public and/or private health insurance services, including the utilization of billing and coding protocols abandoned by the Centers for Medicare and Medicaid Services ('CMS'), so that both Health Care Providers and Millennium would generate multiple billings for tests performed on just one urine sample."

In addition, Millennium offered a fractional ownership billing arrangement to health care providers in which providers would purchase a fractional ownership share in a third-party laboratory that purportedly was independent of Millennium but actually was an affiliate company.

According to the complaint, under this fractional ownership billing arrangement, the providers either bill patients directly for urine samples sent for testing at the laboratory and/or receive a portion of the laboratory's billings as a "dividend" or "return on investment."

"Health care providers, believing that they could legally take advantage of this unlawful inducement, chose Millennium's laboratory services over Ameritox's in order to receive the fractional ownership billing arrangement," the complaint said.

Millennium Labs Sues Competitor's Sales Rep

In a separate, unrelated lawsuit, Millennium Laboratories Inc. April 16 accused a medical laboratory sales representative of offering doctors illegal kickbacks to induce them to use another medical laboratory to test patients' specimens (*Millennium Laboratories Inc. v. Stimmel*, W.D. Pa., 2:12-cv-00500).

In its complaint, filed in the U.S. District Court for the Western District of Pennsylvania, Millennium alleged that Richard Stimmel, acting as an independent sales representative for Universal Oral Fluid Laboratories of PA LLC, paid kickbacks to physicians for referring laboratory specimens to Universal.

The complaint alleged that Stimmel offered to pay doctors "profits" based on the amount of reimbursement Universal receives from public and private third-party insurance payers for each specimen the physicians refer to Universal for testing. The public payers include Medicare and Medicaid, the complaint said.

According to the complaint, Stimmel previously settled litigation with Millennium over the same conduct. Under his settlement with Millennium, Stimmel agreed to stop doing business with Universal and to stop marketing or implementing kickback schemes to physicians.

Stimmel was a defendant in pending litigation Millennium had brought against Universal in U.S. District Court for the Middle District of Florida. In December 2011, Millennium agreed to dismiss Stimmel from the litigation in exchange for his agreement to stop any and all agreements or arrangements he had with Universal, stop promoting the schemes devised by Universal, and to stop working for Universal.

But, the complaint said, Stimmel continues to work for Universal as an independent sales representative and continues to drive business to Universal through illegal kickback schemes.

The complaint is seeking a permanent injunction barring Stimmel and his employees, representatives, or agents from continuing to offer physicians any "Joint Venture" and/or "Medical Office Service Agreement" arrangements or other kickbacks in exchange for referrals.

Millennium asked for actual damages including, but not limited to, Millennium's lost business profits, "Stimmel's ill-gotten and unjustly derived revenues, and Millennium's expenditures spent repairing its relationships with physicians and correcting Stimmel's false advertising." It also is seeking attorneys' fees.

According to the docket, the case has been designated for placement into the U.S. District Court's Alternative Dispute Resolution program.

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COMPLIANCE PERSPECTIVES

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Keeping the Whistle Away From the Whistleblower: The Laboratory Compliance Officer's Role in Qui Tam Avoidance

Do you, as a laboratory compliance officer, want to spare your employer the disruption, expense, and burden of a government enforcement action? The answer, of course, is "yes." The most effective and efficient way of doing so is to take steps to reduce the likelihood that a whistleblower will bring a qui tam action against your laboratory. Why? Because most government enforcement actions begin with the filing of a qui tam complaint by a whistleblower. And laboratories have been the subject of many qui tam cases.

What Is the Role of Whistleblowers in Health Care Enforcement?

Reports issued by the U.S. Department of Justice (DOJ) confirm that the vast majority of cases that it has opened since 2008 have been the result of qui tam complaints. These cases are brought to the government by those with knowledge about conduct that they deem to be fraudulent. These complaints are authorized by the federal False Claims Act, which encourages the filing of such suits through the promise to whistleblowers of a share of the federal recovery, usually in the range of 15 percent to 30 percent. These payments to whistleblowers are known as whistleblower's share.

The role of these cases in federal enforcement is most dramatically illustrated by reviewing the numbers. In 2008, the DOJ opened 291 new False Claims Act cases; 231 (79 percent) of them came from whistleblowers. In 2009, the DOJ opened 312 new cases; 278 (92 percent) of them came from whistleblowers. In 2010, the DOJ opened 424 new cases; 383 (95 percent) of them came from whistleblowers. And in 2011, the DOJ opened 454 new cases; 417 (91 percent) of them came from whistleblowers. Thus, qui tam cases filed by whistleblowers have escalated at dramatic rates.

The role of whistleblowers is confirmed by the following statistics:

- Since 1996, private individuals have initiated more than 7,800 qui tam actions.
- In 2011, whistleblowers were the source of 91 percent of health care False Claims Act cases (compared with 35 percent in 1991).

A similar picture emerges from a review of the settlements and judgments secured by the government during this time frame:

Year	Non-Qui Tam	Qui Tam
2008	$162,108,253	$953,405,040
2009	$238,081,424	$1,394,619,974
2010	$539,043,024	$2,011,445,536
2011	$178,147,545	$2,257,683,198

You, as a compliance officer, should take note of the growing importance of whistleblowers and qui tam cases in government enforcement and may wish to consider whether you have a new job to do in seeking to avoid the filing of qui tam cases against your laboratory. Creating a qui tam avoidance program seems to fit within the compliance officer's role. But a natural question is what is such a program and what can it do? Answering the following questions will help you create such a program.

Who Are the Whistleblowers?

A first task is to recognize who whistleblowers are. Looking at who brought some of the cases that were settled in 2011 is a good first step.

Novo Nordisk	Oscar Montiel, a former medical liaison. Ian Black, a former U.S. Armed Forces physician.
KV Pharmaceuticals	Constance Conrad, who is described as having some 30 years' experience in federal health care programs—she is also a relator in the Healthpoint Ltd. qui tam (filed in 2011) and other past cases.
Medtronic	Kathy Onwezen, clinical specialist in the Cardiac Rhythm Management Sales and Sales Support Division. Elaine Bennett, sales representative at Boston Scientific's Cardiac Surgery Division (competitor). Alan Brill, senior tachyarrhythmia field engineer and responsible for the training and education of Medtronic's field staff. Adolfo Schroeder, (unknown).
Guidant, LLC	Robert A. Fry, former sales agent for Guidant.
GE Healthcare Inc.	James Wagel, a pharmaceutical representative selling Bristol-Myers's radiopharmaceutical drug Cardiolite.
LHC Group Inc.	Judy Master, who discovered the fraud while she worked for a consulting firm LHC had used.
Medline Industries	Sean Mason, formerly employed by Medline in positions related to customer contracts and account management.
Fresenius Healthcare	Julie Williams, former employee of subsidiary Renal Care Group. Dr. John Martinez, nephrologist.
Maxim Healthcare (2011)	Richard West, a disabled Medicaid patient in Ocean City, N.J.

Thus, whistleblowers can be sales representatives, physicians, trainers, consultants, patients, current employees, former employees, competitors, and customers, just to name a few. Most often, they seem to be current or former employees who are unhappy about the way they have been treated.

Whistleblowers file qui tam suits for a variety of reasons: some are crusaders who want to improve the way the defendant operates while others are professional whistleblowers who bring such suits against numerous defendants and do so, at least in part, to gain payment of whistleblower's share.

So, in developing a qui tam avoidance program, it is useful to think about these two types of whistleblowers.

How to Minimize Risk of a Qui Tam Suit

Crusaders often bring qui tam suits because they feel that they have not been heard and their concerns have not been addressed. Crusaders can be frustrated current or former employees. As a general matter, crusaders bring their concerns to the company before they file qui tam suits. Thus, one way to think about whistleblowers who are current or former crusader employees is that they are human resource problems gone bad. So, how does one minimize the risk of that outcome?

First, strengthen your relationship with the laboratory's human resources professionals and work together in this effort.

Periodically ask all employees whether they have any compliance questions or concerns, and, if they do, ask them to tell you what those concerns are, reminding them that they will be protected from retaliation. If they report that they have no compliance concerns or questions, ask that they sign and date a form saying that. If they report compliance concerns, ask that they list them on the form and sign and date it. This completed form will give you a work list from which to begin your inquiries and will create a record that you asked and the information on the form is what you were told.

Second, make sure that all compliance complaints are investigated and that the complainants (if they have identified themselves) know that you are looking into their concern and that you are taking it seriously. If the allegation raises significant issues, consult knowledgeable counsel about how to conduct an internal investigation; it may be advisable to have external counsel conduct the inquiry under the attorney-client privilege.

If the complainant is anonymous, ask counsel how to manage an internal investigation under such circumstances and still deal, if possible, with the need to inform employees that compliance is on the job. The risk with anonymous complaints is that the complainant feels that inadequate attention is being directed to the complaint and that the matter should be brought to the government's attention through the filing of a qui tam suit. This really does happen.

Third, walk the talk. Periodically ask all employees whether they have any compliance questions or concerns, and, if they do, ask them to tell you what those concerns are, reminding them that they will be protected from retaliation. If they report that they have no compliance concerns or questions, ask that they sign and date a form saying that. If they report compliance concerns, ask that they list them on the form and sign and date it. This completed form will give you a work list from which to begin your inquiries and will create a record that you asked and the information on the form is what you were told.

Fourth, carefully plan all reductions-in-force to reduce the risk that such actions will create whistleblowers. Consult employment and health care counsel experienced in such matters to assist you in planning and executing the reductions.

Fifth, conduct comprehensive exit conferences with all departing employees. Remind them of how important compliance is to the laboratory and ask them to help you by providing you with all of the information they have about all of their compliance concerns, if any. Ask that they sign and date a statement listing the concerns that they have reported, and, if they have said that they have no concerns, ask that they sign and date a statement saying that.

Other Whistleblowers

Other crusaders can be independent contractors hired by the laboratory, patients served by the laboratory, customers of the laboratory, and competitors to the laboratory. How can you deal with them? Make sure that they know that you have an active and comprehensive compliance program. Make your policies available to them. Ask that they communicate with you if they have any compliance concerns and respond quickly if and when you learn that they do; take their concerns seriously and make sure that they know that you do.

How can a compliance officer deal with the possibility of a professional whistleblower? This category of whistleblower is more difficult to deter. Keeping a list of those who have served as whistleblowers can be helpful, but this is a daunting and difficult task.

The issue of self-disclosure is increasingly important, given the fact that failure to disclose and refund Medicare Part A and Part B overpayments within 60 days is now an independent ground for violation of the False Claims Act and will thus likely be the basis for qui tam suits and whistleblower scrutiny.

What other steps can a laboratory compliance officer take to avoid qui tam cases? Of course, having an active, comprehensive, and effective compliance program is one key to avoiding qui tam cases. However, laboratories with such programs have found themselves defending cases brought by qui tam whistleblowers. So, what else can you do?

Testing how your compliance program is being perceived is a first step. How visible is the program? Do those subject to the program believe that it is part of the fabric of the laboratory's operations and culture? Do they believe that complaints are handled promptly and adequately? Do they feel that they are heard?

Making sure that your compliance program is keeping up is an important second step. When a qui tam case has been settled, new whistleblowers can be created who bring similar suits against similar types of entities. This has happened to laboratories. So, be vigilant about settlements and new cases and make sure that your compliance program addresses the issues raised by them and does so in a highly visible way.

Similarly, consider how you are going to incorporate new regulatory requirements into your compliance program.

Finally, carefully consider when and how to make disclosures to the government. This is probably an area where counsel should be consulted. The issue of self-disclosure is increasingly important, given the fact that failure to disclose and refund Medicare Part A and Part B overpayments within 60 days is now an independent ground for violation of the False Claims Act and will thus likely be the basis for qui tam suits and whistleblower scrutiny.

Is it worth the time and effort to implement a qui tam avoidance program? Without a doubt, it is—your laboratory will thank you!

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Palmetto's MolDx Program Now in Effect, *from page 1*

assess the scientific literature and determine coverage. In addition to the published requirements, experts may consider retrospective studies, white papers written by national societies and recognized experts, virtual or theoretical models that have been vetted in the scientific literature, and abstracts.

The Z-Code identifier issued by McKesson may be used to identify tests outside the Palmetto GBA MolDx program, and public information about the test and associated performing labs will be available through the McKesson Diagnostics Exchange public registry. The PTI, however, will only be used to recognize and apply coverage and reimbursement for claims submitted in the MolDx program. The PTI and its supporting information will not appear or be used in the McKesson public registry. Palmetto earlier this year added the option for an alternate identifier after laboratories expressed concern about having to receive a Z-Code from McKesson, a consulting company serving as a contractor to Palmetto.

Jurisdiction 1 Part B MolDx Exempt Tests

MolDx Exempt (No Unique Identifier or Tech Assessment Required)	Unique Identifier (PTI/Z-Code) Required *No* Tech Assessment Required	Unique Identifier (PTI/Z-Code) Required Tech Assessment Required
Tests specifically described by a single CPT/HCPCS code and submitted with one unit of service	Any test that meets the following: • 101 New MDT CPT codes • FDA cleared/approved (unmodified) tests • Current New York State (NYS) approved tests • Grandfathered NYS tests developed prior to 2003 • National Institutes of Health Genetic Testing Registry (GTR) • Tests assessed by an independent review entity, such as United States Diagnostic Standards (USDS) • AMA Tier 2 Molecular Pathology Procedures	A laboratory developed test (LDT) producing a single result and billed with multiple CPT codes including any combination of the following: • Methodology-based stacking CPT codes (83890-83914) • Microarray CPT codes (88384-88386) • Microdissection CPT codes (88380-88371) • Other pathology/laboratory codes (84999, 85999, 86849, 87999)
Infectious disease molecular diagnostic testing described by CPT codes (87001-87905)	Coverage Determination by Palmetto GBA LCD or article. For example: • Tumor of origin assays • OncotypeDx Breast™ • OncotypeDx Colon™ • Allomap™ • HERmark™	MDT/LDT that provides • Diagnostic determination • Prognostic/predictive determination • Risk assessment • Screening
Cytogenetics – CPT codes 88230-88291		Pathology and Laboratory Not Otherwise Classified (NOC) codes
Surgical Pathology (CPT codes 88300-88372) including the following: • Flow cytometry – CPT codes 88182-88189 • Immunohistochemistry (IHC) CPT code 88342 • In situ hybridization (ISH) testing CPT code 88365		Modified FDA cleared/approved tests
Reagents • Analyte specific reagents (ASR) • Research use only reagents (RUO)		

Source: Palmetto GBA

Effective May 7, claims that do not have a test identifier will receive an informational notice that the required PTI or Z-Code has not been submitted with the claim. Beginning June 1, claims for molecular diagnostic tests will be considered for adjudication only when a Z-Code or a PTI *has* been assigned to the test and is entered into the comment/narrative field of the claim form. If a PTI or Z-Code is pending or the lab is unable to update internal systems for claims submission, Palmetto GBA will accept a fax and a completed test identifier application form with each claim.

Oral Arguments in *Myriad* Remand Scheduled for July 20

Oral arguments for the renewed review of the *Myriad* case on patent eligibility of isolated DNA will be held July 20, the U.S. Court of Appeals for the Federal Circuit announced April 30 (*Association for Molecular Pathology v. United States Patent and Trademark Office*, Fed. Cir., No. 2010-1406, *appeal reinstated* 4/30/12).

The U.S. Supreme Court remanded the case March 26 for reconsideration by the appeals court in light of the high court's decision on statutory subject matter, under 35 U.S.C. §101, in *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, 132 S. Ct. 1289 (2012).

Parties and friends of the court are invited to submit briefs by June 15. Parties' briefs are limited to 20 pages; amici to 15 pages. Briefs are expected to address the question, "What is the applicability of the Supreme Court's decision in *Mayo* to Myriad's isolated DNA claims and to method claim 20 of the '282 patent?"

The court expressly invited the United States to file an amicus brief.

The Challenge in *Myriad*

The *Myriad* case arose from a 2009 declaratory judgment challenge against patents (5,747,282; 5,837,492; 5,693,473; 5,709,999; 5,170,001, 5,753,441; and 6,033,857) for which Myriad Genetics Inc. is the exclusive licensee.

In Mayo, the Supreme Court concluded that the steps of the method claims at issue failed to "add enough" to the "inventive concept" of the asserted patents—the correlations between metabolite levels and effectiveness of the drug.

The American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT) filed the lawsuit on behalf of the Association for Molecular Pathology and other medical associations, eight individuals involved in medical research, two breast cancer counselors, and six women diagnosed with or seeking diagnosis for cancer.

The plaintiffs argued that nine composition of matter and six method claims of the patents on the BRCA1 and BRCA2 genes—associated with hereditary breast and ovarian cancer—were ineligible for patenting under Section 101.

Three Federal Circuit panel judges agreed that only one of the method claims—Claim 20 of the '282 patent—and all claims to cDNA are patent-eligible, but they split 2-1 as to claims to isolated DNA (*Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329, Fed. Cir. 2011).

The majority reversed a lower court's ruling against patent eligibility for such claims (702 F. Supp. 2d 181, S.D.N.Y. 2010).

A week after its surprising unanimous decision rejecting method claim patent eligibility in *Mayo*, however, the Supreme Court granted the ACLU and PUBPAT's petition

for writ of certiorari, vacated the Federal Circuit's opinion, and remanded the case for reconsideration.

Differences in *Mayo*

In *Mayo*, the Supreme Court concluded that the steps of the method claims at issue failed to "add enough" to the "inventive concept" of the asserted patents—the correlations between metabolite levels and effectiveness of the drug.

While the court provided no standards for determining when steps provide "enough," it said that the asserted claims failed because "any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately."

The high court recognizes three exceptions to patent eligibility under Section 101—laws of nature, natural phenomena, and abstract ideas—often referred to together as "fundamental principles." The *Mayo* method claims invoked the law of nature exception.

The bigger fight in* Myriad *is on composition of matter claims—isolated DNA and cDNA. Many stakeholders have said that the exception for natural phenomena would then apply, but there is no agreement on whether the law of nature exception should be analyzed differently from the natural phenomenon exception.

The five method claims rejected by the Federal Circuit in the *Myriad* case, on the other hand, were held to be improperly "instead directed to the abstract mental process of comparing two nucleotide sequences."

The Federal Circuit's April 30 order may have indicated that it will only reconsider the sixth method claim challenged, Claim 20 of the '282 patent, which is directed to "[a] method for screening potential cancer therapeutics." As in *Mayo*, this claim at issue uses a "wherein" clause that indicates a correlation: "wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic."

However, the bigger fight in *Myriad* is on composition of matter claims—isolated DNA and cDNA. Many stakeholders have said that the exception for natural phenomena would then apply, but there is no agreement on whether the law of nature exception should be analyzed differently from the natural phenomenon exception.

Will Standing Issue Be Revived?

Perhaps significantly, the Federal Circuit's April 30 order also did not ask the parties to address another outstanding issue in the case—whether any of the plaintiffs have standing.

The appeals court originally held that only one plaintiff—Harry Ostrer, a researcher at New York University School of Medicine who was allegedly interested in sequencing the BRCA1 and BRCA2 genes—met the requirements for declaratory judgment standing under the Supreme Court's decision in *MedImmune Inc. v. Genentech Inc.*—"a substantial controversy . . . of sufficient immediacy and reality" and "meaningful preparation" to conduct potentially infringing activity.

In its briefing for Federal Circuit rehearing and for Supreme Court review, Myriad argued that even Ostrer should have been denied standing, based on his move to a different lab just before the Federal Circuit's decision. G2

News-At-A-Glance

RECORD FRAUD TAKEDOWN: The departments of Justice and Health and Human Services May 2 announced charges against 107 individuals across the country for allegedly participating in Medicare fraud schemes totaling $452 million in false billing. Medicare Fraud Strike Force teams in seven cities conducted the fraud takedown, Attorney General Eric Holder said, and the $452 million in alleged false billing represented the highest amount ever associated with a single fraud takedown in the five-year history of the strike force program. The strike force executed 20 search warrants and has arrested or taken into custody 91 of the charged defendants. The defendants were charged with a variety of fraud-related crimes, including violations of the anti-kickback statute and money laundering. The alleged fraud schemes covered a range of services, including home health, mental health, durable medical equipment, and physical and occupational therapy. Over half of the alleged false billing ($225 million) occurred in Baton Rouge, La., with the remainder in Miami; Houston; Los Angeles; Detroit; Tampa, Fla.; and Chicago.

LAWMAKERS SEEKS ANSWERS ON PROGRAM INTEGRITY CONTRACTORS: A House subcommittee chairman April 25 asked the Centers for Medicare and Medicaid Services (CMS) to provide performance metrics for the agency's Medicare program integrity contractors. Rep. Charles Boustany (R-La.), chairman of the Committee on Ways and Means Subcommittee on Oversight, requested the information by May 25. Medicare program integrity contractors include Medicare Administrative Contractors (MACs), Zone Program Integrity Contractors (ZPICs), Recovery Audit Contractors (RACs), Program Safeguard Contractors (PSCs), and the National Supplier Clearinghouse (NSC) Contractor. Boustany said CMS should provide a list of all program integrity contracts, including the duration of the contracts as well as their dollar value; statements of work; the number and amount of overpayment referrals made to MACs and the amount MACs have recovered; a list of all referrals ZPICs and PSCs have made to law enforcement agencies; the total fees paid to each RAC, how RACs are evaluated, as well as the percentage of RAC overpayment determinations that were appealed and the percentage that were overturned; and the number of unannounced site visits conducted by the NSC each month.

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