G2 Compliance Report

G2 INTELLIGENCE

For Hospitals, Laboratories and Physician Practices

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HHS Proposes Rule to Allow Patients Direct Access to Laboratory Test Results

In what it says is part of an effort to empower patients to be informed partners with their health care providers, the Department of Health and Human Services (HHS) is proposing a new rule that would allow patients or their representative direct access to their laboratory tests.

The proposed rule, which will be published in the *Federal Register* on Sept. 14, would modify regulations under two statutes that impose restrictions on patient access to lab results: the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and the Health Insurance Portability and Accountability Act (HIPAA) of 1996. There will be a 60-day public comment period on the proposal.

In proposing the rule, HHS said it wanted to recognize current health reform concepts, such as individuals' involvement in their own health care, by allowing patients easier access to health information.

"When it comes to health care, information is power," HHS Secretary Kathleen Sebelius said in a statement. "When patients have their lab results, they are more likely to ask the right questions, make better decisions and receive better care."

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ACLU, Myriad File for Rehearing in Gene Patent Case

In a bit of a surprise, the parties in the Myriad case each filed a petition Aug. 25 for a panel rehearing in the U.S. Court of Appeals for the Federal Circuit, rather than asking for en banc consideration or taking the case directly to the U.S. Supreme Court (*Association for Molecular Pathology v. U.S. Patent and Trademark Office*, Fed. Cir., No. 2010-1406).

In a divided decision with three separate opinions, the panel ruled July 29 that patents claiming isolated DNA are statutory subject matter under Section 101 of the Patent Act. The plaintiffs' rehearing petition argues that the panel majority erred because "the language of the patents defines the function, not the structure of the patented genes and gene fragments; gene fragments with the altered chemical structure identified by the court exist in nature."

The declaratory judgment defendant, Myriad Genetics Inc., on the other hand, seeks to render the case moot, without vacating the panel's opinion on the merits, by removing from the case the only plaintiff ruled to have standing.

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HHS Proposes Patient Access to Results, *from page 1*

The proposed rule was issued jointly by HHS, the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, and the HHS Office for Civil Rights.

HHS said the move to relax current restrictions on patient access to laboratory results came about as a result of a review by the Health Information Technology Policy Committee. The federal advisory panel seeks to identify barriers to the adoption and use of health information technology. The committee concluded that current CLIA and HIPAA regulations prevent patients from taking a more active role in their personal health decisions, HHS said in an introduction to the proposed rule.

State Law Preemption

Specifically, under a current CLIA regulation (42 C.F.R. § 493.1291(f)), patients in states that do not provide individual access to test results must request and receive the results through their health care provider, according to HHS.

Currently, 39 states—encompassing some 22,671 laboratories—prohibit a laboratory from releasing a test report directly to the patient or prohibit the release without the consent of the health care provider, HHS noted. HHS said it intends that the proposed rule would preempt the law in these states.

The proposed rule would also modify exceptions under HIPAA that impose restrictions on the release of certain laboratory results. A privacy rule (45 C.F.R. § 164.524) issued under HIPAA—which provides individuals with a general right of access to health records—contains exceptions for laboratory results from CLIA-certified laboratories, HHS said.

"Because CMS is proposing to amend the CLIA regulations to allow CLIA-certified laboratories to provide patients with direct access to their test reports, there is no longer a need for the exceptions at §164.524 for CLIA and CLIA-exempt laboratories," HHS said. "Unless these exceptions are removed from the privacy rule, they would serve as a barrier to individuals' right of access to test reports."

After the notice and comment period, laboratories would be required to comply with the new rule within 180 days after the effective date of the final rule, which would be 60 days after the final rule is published in the *Federal Register*, HHS said.

Compliance Costs

HHS said the proposed rule, if it becomes final, would not constitute an "economically significant rule," which Office of Management and Budget guidelines define as one imposing overall annual costs of more than $100 million. HHS estimated that the rule, if implemented in 2011, would impose compliance costs of $3 million to $56 million.

The first-year costs would include initial costs of developing an internal process to handle patient requests for laboratory results, which HHS estimated would range from $2.2 million to $10.2 million. Because the start-up costs would not be necessary in subsequent years, HHS said it expected that compliance costs would diminish over time.

In measuring benefits of the proposed rule, HHS noted it would have a positive but not quantifiable impact on patients, a majority of whom express a preference for being able to obtain test results directly from a laboratory.

Other benefits include reduced workload for health care provider offices, which would be relieved from having to request test results, and fewer patients who fail to seek appropriate medical care, HHS said.

Surya Mohapatra, Ph.D., chairman and CEO of Quest Diagnostics (Madison, N.J.), praised the rule, noting that "patient engagement in health care decisionmaking is vital to promoting better health outcomes and reduced costs in our health care system."

Lab Groups Urge 'Super Committee' To Reject Beneficiary Coinsurance

The American Clinical Laboratory Association (ACLA) is continuing to lead the fight against implementation of beneficiary coinsurance for lab services.

In a recent letter to the Joint Select Committee on Deficit Reduction that began deliberations in September, ACLA urged lawmakers to "reject further reductions in Medicare reimbursement to clinical labs and any beneficiary cost sharing for these services."

The so-called "super committee," composed of six Democrats and six Republicans from the House and the Senate, is charged under the debt ceiling deal to find up to $1.5 trillion in savings over 10 years, beginning in 2013. Its recommendations are due by Nov. 23. If approved by a majority, they go to Congress for an up-or-down vote, with no amendments or filibuster, by Dec. 23. The president retains veto power over any legislation that passes.

Adding cost sharing for laboratory services in Medicare—through either a 20 percent coinsurance or a flat copayment per test —was one of the Medicare proposals reportedly on the table during negotiations leading up to the debt ceiling deal and the creation of the joint select committee.

In the letter, ACLA laid out a series of arguments for sparing Medicare lab services from the chopping block:

- Lab services have had no beneficiary cost sharing since 1984. Introducing coinsurance or a copay of 20 percent would hinder beneficiary access to needed and recommended testing. It would impose added out-of-pocket expenses (which, in the case of advanced molecular diagnostics for cancer and other serious diseases, could run into hundreds of dollars). It also runs counter to the emphasis Congress has given to prevention and wellness—this year, for example, by waiving cost sharing for most Medicare-covered screening services.
- For labs, coinsurance or copayment means, in many cases, added costs for billing and collecting that typically exceed the amount due. "The volume of bills for small amounts would be over 215 million new bills to beneficiaries for an average of $6.20, with 70 million of those bills being for less than $2," ACLA said. "The cost of collection, and the ability of laboratories to collect, is uniquely difficult because they do not usually have a face-to-face encounter with the beneficiary that all other providers who bill patients have."
- The new costs will be "devastating" to thousands of smaller businesses that are often the sole provider of lab services to nursing home and homebound beneficiaries. These populations have high concentrations of "dual eligibles" (Medicare and Medicaid) for whom collection of the coinsurance or copay is unlikely. "While $6 lost per claim may not sound like a significant amount," ACLA said, "in fact, when the average claim is only $20, a loss of $6 per claim amounts to a 30 percent reduction in reimbursement to these labs—an amount that could swiftly put them out of business. Nursing homes could be left with no choice but to send beneficiaries by ambulance to the hospital for routine blood work, at considerable cost to Medicare."

Over the past three decades, coinsurance or copays for lab services have been considered, ACLA noted, but have been rejected time and again by independent outside organizations, government agencies, and Congress.

ACLA also urged the joint select committee to spurn any further lab reimbursement cuts. "Payments have been reduced by about 40 percent in real (inflation-adjusted) terms over the past 20 years. And they are scheduled to decline by an additional 19 percent over the next 10 years under the health care reform law."

Lab Will Pay $154,000 Over Improper Test Billing

A Massachusetts clinical laboratory has agreed to pay nearly $154,000 to resolve allegations it overcharged Medicaid for urine drug tests that were not properly ordered by a doctor or other authorized prescriber for a medically necessary purpose, Massachusetts Attorney General Martha Coakley said Aug. 19.

Diagnostic Laboratory Medicine Inc. (DLM) also overcharged the state's Medicaid program for urine tests between 2005 and 2011 by failing to give its best price and failing to comply with documentation and recordkeeping requirements, Coakley said. The alleged violations of state laws and Medicaid rules and regulations resulted in significant Medicaid overpayments to DLM, according to Coakley.

DLM Business Manager Tony Ferullo said the company did not commit fraud or bill for any tests that did not take place but that it had submitted requisitions from clinics for payments without physicians' signatures, something that is required under Medicaid but not Medicare. The alleged violations also included other incomplete paperwork dating back several years, he added.

The DLM agreement is the sixth settlement resulting from an ongoing industrywide investigation by Coakley's Medicaid Fraud Division into urine drug tests billed by independent clinical laboratories to the state Medicaid program. To date, the investigation has returned approximately $10 million to the state Medicaid program and resulted in 42 criminal indictments. G2

Lab Owner Pleads Guilty to Illegally Selling Stem Cells

A former Arizona laboratory owner pleaded guilty Aug. 18 in a Texas federal court to charges of illegally introducing stem cells from umbilical cord blood into interstate commerce for treating patients with immune disorders, prosecutors announced (*United States v. Branyon*, S.D. Tex., No. 4:11-cr-00535).

Defendant Fredda Branyon, who owned Global Laboratories LLC in Scottsdale, Ariz., pleaded guilty to introducing an unapproved new drug into interstate commerce in violation of Food and Drug Administration regulations, said U.S. Attorney for the Southern District of Texas José Angel Moreno.

The defendant purchased umbilical cord blood and tissue from a birthing facility in Del Rio, Texas, telling the seller that the stem cells would be used for research while knowing they would be used for nonresearch purposes without FDA approval, according to court records. Branyon later employed a Charleston, S.C., medical school professor as a consultant to help her create stem cells from the umbilical cord tissue. The stem cells were neither created under FDA guidelines nor in an FDA-approved facility, the plea agreement said.

Branyon admitted that she sold approximately 183 vials containing stem cells to an unidentified individual who indicated he was a physician with Rio Valley Medical Clinic in Brownsville, Texas, on 27 separate occasions between April 2009 and February 2010. Branyon provided the individual with a form indicating that the sale of the stem cells was for research purposes only. However, in her plea agreement, Branyon admitted that she knew the individual would use the stem cells to treat patients.

The individual paid Branyon $300,000 for the stem cells that were used in connection with medical procedures he performed on patients with multiple sclerosis and amyotrophic lateral sclerosis, according to the plea agreement. FDA has approved the use of stem cells for research purposes only and under strict guidelines that require agency approval. Judge Melinda Harmon of the U.S. District Court for the Southern District of Texas set a Nov. 18 sentencing date for Branyon. She faces up to three years in prison and a $10,000 fine. G2

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COMPLIANCE PERSPECTIVES

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To Give or Not to Give—Stark, Speculums, and Supplies

For nearly 20 years I have argued with both lab clients and lab competitors (and their legal counsel) against the practice by many clinical and pathology laboratories of providing free speculums to clinicians to aid in collecting Pap smear specimens to send to the laboratory for testing. Proponents justified the practice on the grounds that (1) Pap specimens cannot be collected without speculums, (2) a speculum is needed to ensure collection of a viable and reliable Pap specimen, (3) speculums are relatively inexpensive, and (4) labs can readily correlate the volume of speculums provided with the number of Pap tests for which they are used. In its Stark law advisory opinion issued last year and posted at its Web site earlier this year, the Centers for Medicare and Medicaid Services (CMS) directly rejected those justifications and concluded that the Stark law prohibits the practice of providing inexpensive disposable single-use speculums to physicians who refer testing reimbursed by Medicare or Medicaid, unless a specific Stark law exception applies.

This opinion underscores the government's strict interpretation of the Stark statute. Given the significant penalties for the failure to understand and meet the technical, and perhaps illogical, requirements of Stark, clinical and pathology laboratories are well-advised to review their policies and practices relative to providing supplies and equipment to ordering physicians.

The CMS advisory opinion (CMS-AO-2010-01) given in response to a formal request from an unnamed laboratory, reviewed the practice by the lab of providing to its physician customers, at no charge, two types of disposable, single-use speculums costing 30 cents and $1.68. CMS explained that the Stark law does not prohibit labs from providing physicians with items, devices, or supplies used solely to collect, transport, process, or store specimens, or to order or communicate test results. CMS noted the lab's representation that the speculums were "not often used when a specimen is not collected" and that the lab monitored the number of specimens to limit the quantity of speculums provided. CMS nonetheless concluded that "[b]ecause the specula are not used by the physicians *solely* to collect, transport, process, or store specimens referred to the [laboratory], the provision of specula to the Referring Physicians constitutes remuneration" prohibited by the Stark law. CMS reasoned, "Pap smear specimens are typically collected as part of an extensive gynecological examination of the patient. Such examination requires the use of a speculum, regardless of whether a Pap smear specimen is collected."

CMS makes clear that the pivotal question under the Stark law is not whether the supply or equipment in question is *necessary* for the referring physician to collect, transport, process, or store specimens to be sent to the laboratory. Rather, the test is whether the supply or equipment is used *exclusively* for these purposes, even if the requested lab tests cannot be performed or reported without it.

In prior commentary to the proposed Stark II regulations in 1998, CMS explained:

> We interpret "solely" in this context to mean that these items are used solely for the purposes listed in the statute, such as cups used for urine collection or vials used to hold and transport blood to the entity that supplied the items or devices.

> [CMS does not] regard specialized equipment such as disposable or reusable aspiration or injection needles and snares as solely collection or storage devices. Instead, these items are also surgical tools that are routinely used as part of a medical or surgical procedure.

Two years later, CMS explained further in its commentary to the final Stark II regulations:

> We wish to clarify our views on the "items, devices, and supplies" provision here. First, in enacting section 1877(h)(1)(C)(ii) of the Act, we believe that the Congress . . . intended to include in this section items, supplies, and devices of low value, such as single use needles, vials, and specimen cups, that are primarily provided by laboratories to physicians to ensure proper collection of specimens for processing at the laboratory and that have little, if any, independent economic value to the physicians who receive them. In many cases, the cost of these items may already be included in the practice expense portion of the Medicare payment made to the physician. . . .
>
> As to those single use, low value items, devices, and supplies that come within the scope of section 1877(h)(1)(C)(ii) of the Act, the fact that the number of supplies provided to a physician approximates the number of specimens sent by the physician to the laboratory providing the supplies is merely one indicator that the supplies have been provided in connection with specimen collection for the entity providing the supplies. The numerical correlation is not a statutory or regulatory requirement. However, the provision of an excessive number of supplies creates an inference that the supplies are not provided solely to collect, transport, process, or store specimens for the entity providing them.
>
> While we recognize that sterile gloves are essential to the proper collection of specimens, we believe they are not items, devices, or supplies used solely to collect, transport, process, or store specimens. To be sure, sterile gloves are essential to the specimen collection process, but their main function is to prevent infection or contamination. Also, sterile gloves are fungible, general purpose supplies typically found in a physician's office and used for a wide range of examinations and procedures. We believe it would be impractical for physicians' offices to monitor and regulate the use of gloves so as to limit their use to the collection of specimens for the laboratory that provided them. Accordingly, we believe the provision of free gloves is remuneration subject to the general prohibition of section 1877 of the Act, in the absence of an applicable exception.

Because the Stark law is a strict liability statute, lab practices that violate the Stark law, even if they can be justified as "reasonable" or "common sense" business practices, may result in denial or refunds of Medicare and Medicaid payments for prohibited referrals, monetary penalties of up to $15,000 per claim, fines of up to double the amount claimed, and exclusion from the Medicare and Medicaid programs. The Stark law can also result in a violation of the federal False Claims Act, resulting in civil penalties of $5,500 to $11,000 per false claim and damages of three times the amount of each false claim, exclusion from federal programs, and imprisonment for up to five years.

The need to comply with the strict letter of the Stark law is illustrated by the March 2011 settlement between the Health and Human Services Office of Inspector General (OIG) and Fairview Northland Regional Health Care in Minnesota. After it

self-disclosed conduct to the OIG, the medical center agreed to pay $50,000 for allegedly violating the Civil Monetary Penalties Law provisions applicable to physician self-referrals and kickbacks. The OIG alleged that the hospital entered into an *unwritten lease agreement* with a physician practice. Stark requires that a lease with a referring physician be in writing, signed by both parties, for a term of at least one year, at a fair market value rental rate. The case underscores that the OIG cares about technical as well as substantive compliance with the Stark law.

Once laboratories understand the restrictions of the Stark law and regulations relating to the provision of supplies to physicians, two very significant practical challenges remain: (1) convincing physician clients that the lab is not simply trying to reduce its own costs at the doctor's expense and (2) combating the practices of competitor labs that do not understand the Stark rules or do not care about the consequences of violating the law. The CMS advisory opinion concerning speculums may be another helpful document to share with customers, and perhaps with competitors. Another step taken by laboratories in California several years ago was to work within their trade association to seek legal guidance regarding prohibited supplies. In 2001, the California Clinical Laboratory Association (CCLA) first sought a legal opinion regarding the Stark law restrictions on client supplies and then approved a resolution adopting that opinion. The CCLA guidance identified a list of supplies as prohibited by the Stark law (see box below).

Although some competitors and physicians in California continue to disregard this guidance, compliance-minded California laboratories have been able to use

Gift Items Prohibited by the Stark Law

- alcohol pads
- antibacterial soap
- aspiration needles (reusable or disposable)
- baggies or zip-lock bags
- Band-Aids
- betadine swabs
- biopsy needles
- butterfly needles
- catheter kits
- coban wrap pressure bandage for wounds
- cotton balls
- cover slips
- examination gowns
- facial tissues
- gauze
- germicidal soap
- gloves
- hazardous material labels
- hemocult developer
- hypoallergenic tape
- injection needles (reusable or disposable, large and small)
- K-Y or other lubricating jelly
- microscope slides
- parafilm
- phlebotomy chairs
- plain paper for copier
- Q-tips
- reagents for in-office testing
- refrigerators
- rubber bands
- snares
- speculums
- syringes
- table paper
- test kits
- test tube racks
- tongue blades
- tourniquets
- urine cups (nonsterile, without lid)
- urine dip sticks

Source: California Clinical Laboratory Association

the guidance to help "level the playing field." At that time, CCLA encouraged other industry trade associations to consider similar steps. CCLA also requested the OIG provide the industry with formal guidance, through commentary, fraud alerts, regulation, or otherwise, to give a clearer and more detailed standard for all laboratories inside and outside of California to follow—and utilize to convince physicians to follow. Although no such catalog has been issued, both the OIG speculum opinion and the guidance cited in this article substantiate the list provided by the CCLA.

As an additional caution, laboratories also must recall that the provision of supplies and equipment to lab customers implicates the federal anti-kickback statute. The general rule under the anti-kickback statute is that the statute is implicated any time a laboratory gives supplies to its clients for free or at less than fair market value—note that the statute contains no exemption for de minimus forms of remuneration. However, the OIG in a 1994 fraud alert clarified that the statute may not be implicated when a laboratory provides its clients with certain types of supplies that are integral to, and solely used for, performance of the outside laboratory's work:

> The following are additional examples of inducements offered by clinical laboratories which may implicate the anti-kickback statute: . . .
>
> Provision of computers or fax machines, unless such equipment is integral to, and exclusively used for, performance of the outside laboratory's work.

OIG has made additional statements concerning free supplies since that time. Based upon these instructions from OIG, the general rule seems to be that a laboratory services provider can provide free supplies to the extent (1) they are *not provided to the physicians by the laboratories in exchange for referrals,* (2) they are *integral to, and exclusively used for, performance of the outside laboratory's work,* and (3) they do *not have a clear independent value to physicians*.

In conclusion, laboratories are strongly encouraged as part of their now mandatory compliance programs to adopt careful guidelines in connection with their offering and providing of supplies to physician clients. Suggested guidelines include:

1. In no case should the provision of supplies to the physician client be offered to induce referrals of the physician client's testing business—thus, the lab should not use the provision of supplies as a sales or marketing pitch.

2. Supplies must be used by physicians *solely* to collect, transport, process, or store specimens referred to the laboratory.

3. The lab should adopt and adhere to a detailed list of permitted and/or prohibited supplies—the CCLA list is a very good place to start.

4. No supplies provided by the lab should be used for the collection, transportation, processing, storage, or preparation of specimens for testing to be *performed and/or billed by the physician client*. The lab should take care to ascertain whether the physician client performs in-office testing and regulate the provision of lab supplies accordingly.

5. The lab should maintain and document its procedures to police unauthorized use of the supplies. At a minimum, quantities of supplies must be carefully monitored and correlated to the volume of specimens typically sent to the laboratory for processing.

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ACLU, Myriad File for Rehearing in Gene Patent Case, *from page 1*

Section 101 Holdings by Split Court

The case involves a 2009 declaratory judgment challenge initiated by the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT) against seven patents for which Myriad is the exclusive licensee.

The ACLU and PUBPAT, acting on behalf of the Association of Molecular Pathology and other medical associations, medical researchers, breast cancer counselors, and women diagnosed with or seeking diagnosis, 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 directed to nonstatutory subject matter under Section 101.

The three panel judges agreed that only one of the method claims at issue was drawn to patentable subject matter and that claims to cDNA are patent eligible.

They split 2-1, however, as to claims to isolated DNA, with the majority reversing the lower court's ruling. Each of the judges filed a separate opinion as to those claims, each identifying a different standard for distinguishing patent-ineligible "products of nature." The majority agreed at minimum, though, that isolated DNA has "markedly different chemical characteristics" compared to corresponding native DNA in the human body.

The panel reached the Section 101 issues after agreeing that one—and only one—of the researchers had standing to file the suit. Harry Ostrer, a researcher at New York University School of Medicine, the court held, met the requirements for declaratory judgment standing under the Supreme Court's decision in *MedImmune Inc. v. Genentech Inc.* (2007)—"a substantial controversy . . . of sufficient immediacy and reality" and "meaningful preparation" to conduct potentially infringing activity.

The court first distinguished only three of the plaintiffs, all medical researchers and including Ostrer, as subject to Myriad's "affirmative patent enforcement actions," which occurred in 1998-1999.

Of those three, only Ostrer, the court said, "state[d] unequivocally that he will immediately begin [BRCA] testing" if the court ruled the patent claims nonstatutory. The other two said only that they would "consider" resuming BRCA testing, the court noted, defeating their standing claim.

Myriad Challenges Researcher's Standing

Just before the July 29 court decision, Myriad notified the court that Ostrer was planning to leave NYU at the end of August and move to the Montefiore Medical Center at the Albert Einstein College of Medicine.

The ACLU then submitted a letter to the court asserting that the Montefiore laboratory has the same capabilities as the NYU lab and that Ostrer still has a "wish to engage in sequencing" BRCA1 and BRCA2. The court did not discuss either communication in its opinion.

In its rehearing petition, Myriad argues that the controversy existed between Myriad and NYU and that, "by deciding to start over at a new institution, Dr. Ostrer has severed any nexus he might have had to the Myriad-NYU controversy supposedly created by Myriad's 1998 letter."

Myriad further argues that the ACLU letter did not establish that Montefiore will allow Ostrer to do the BRCA testing he envisioned and that Ostrer's "wish" to sequence the genes fails to meet the panel's requirement for an "unequivocal" statement of intent.

"Because the mootness was caused by plaintiff Ostrer's unilateral action," Myriad's petition continues, "the panel opinion upholding Myriad's patent claims should not be vacated."

Plaintiffs Say Two More Have Standing

The ACLU petition for the plaintiffs focuses on the isolated DNA patent eligibility aspect of the case but also devotes two paragraphs to make a case for standing for two other plaintiffs.

First, the plaintiffs argue, if Ostrer has standing, an organization for which he is a member—the American College of Medical Genetics—has organizational standing under *Warth v. Selden*, 422 U.S. 490, 511 (1975).

Second, the petition counters the court's assertion that only three researchers had received threatening communications from Myriad. Another plaintiff, Ellen Matloff, declared that "she personally had conversations with Myriad in which she was told by Myriad that she and geneticists at Yale would violate Myriad's patents if they performed the tests that she wanted to perform," the ACLU said.

ACLU, PUBPAT Challenge Patent Eligibility

The plaintiffs' rehearing petition cites a number of errors in the Section 101 analysis performed by both the majority opinion author, Judge Alan D. Lourie, and the concurrence written by Judge Kimberly A. Moore.

The petition repeats the plaintiffs' basic premise that the chemical structure of the isolated DNA is irrelevant for determining whether the DNA is an unpatentable product of nature. "The majority erroneously ignored the language of the claims and erroneously ignored the scientific fact that DNA fragments with identical chemical structure are found in nature," the ACLU argues further.

In part, the plaintiffs fault the judges for construing the claims at issue in a way that was not discussed in the lower court. For example, Lourie found it important that covalent bonds are broken in isolating the genes at issue, but, the ACLU argues, "The claims have no express limitations to gene fragments that have had their covalent bonds broken by man, and such an inherent limitation is not supported by the specification, the file history, or any argument Myriad made at any time in this matter."

Even assuming the structural difference of breaking the bonds, the ACLU argues, such events happen to the genes inside the human body.

"Even if the chemical alterations deemed significant by the majority are significant, they result in chemicals that are not markedly different from and are at times identical to those found in nature," the plaintiffs conclude. "They are thus not patentable subject matter."

Patent Reform Bill Passes; Obama Will Sign

The U.S. Senate passed Sept. 8, without amendment, the House patent reform bill, H.R. 1249, by a vote of 89-9. The bill now goes to the president, who has previously promised to sign the legislation. The sweeping overhaul means the Patent Act will be modified substantially for the first time since 1952.

Most significantly, the Leahy-Smith America Invents Act moves the United States from a first-to-invent to a first-inventor-to-file (FITF) system and extends "prior user rights" protection to nonpatenting commercial users of a later-patented invention.

It further modifies and creates procedures for challenging both patent applications and issued patents at the Patent and Trademark Office, potentially preempting litigation on patents that never should have been granted.

The bill also adds statutory provisions specific to individual industries or technologies, which patent law purists have long deplored. Business method patent owners in the financial service industry who bring infringement claims in court are likely to see their litigation stayed while the PTO re-examines patent validity. Tax strategy patents essentially are nullified, and a provision clarifies when patent term extensions begin.

Six-Year Process to Overhaul Patent System

Patent reform has been debated in Congress since 2005 after reports by the Federal Trade Commission and the National Academy of Sciences cited several problems in patent procurement and litigation.

Attempts at comprehensive legislation began in 2005 with a bill introduced in the House by Rep. Lamar S. Smith (R-Texas). The House passed patent reform in 2007; Senate leaders did not let any bill come to the floor until this year.

Three amendments were considered and defeated Sept. 8 before the final vote. Had any passed, the Senate would have had to reconcile the new version with the House-passed H.R. 1249.

Key elements of the bill include:

- *First inventor to file*. The bill will bring the U.S. patent system in line with the rest of the world by switching from a first-to-invent to a first-inventor-to-file system. Section 3 of H.R. 1249 replaces Section 102 of the Patent Act, 35 U.S.C. §102, in its entirety.

Under FITF, proponents argued, inventorship fights will be simplified and those filing the same patent application in multiple countries will have fewer priority concerns. However, the so-called "harmonization" with foreign jurisdictions is not precise. The U.S.'s FITF system will retain a grace period such that an inventor who discloses an invention publicly in some manner has 12 months to file a patent application and claim first-inventor-to-file status.

- *Prior user rights*. Given the change to FITF, some stakeholders were concerned that an FITF system could lead to a potential infringement liability for first inventors who might have reasons not to file a patent application but who have already commercialized their inventions. The House was convinced, and it included a provision to expand the prior user rights infringement defense for such inventors under 35 U.S.C. §273, which currently applies only to prior commercialization of business method patents.

Prior user rights will now apply to any technology, with commercial activity also including "premarketing regulatory review" for drugs and "nonprofit laboratory use" such as in a university or hospital. However, the revised Section 273 will generally not allow the defense against patents owned by institutions of higher education.

- *Post-grant opposition proceedings*. One of the earliest key drivers of patent reform was the cost of litigation and the desire to offer cheaper alternatives at the PTO. Section 6 of the bill—its most detailed—will provide a new "first window" post-grant review (PGR) procedure allowing challenges within nine months of an issued patent on any ground. It also will provide a revised inter partes review procedure with a higher threshold for the PTO to accept a challenge.

- *Patent marking*. Section 16 of the bill effectively eliminates qui tam complaints of false patent marking under 35 U.S.C. §292(a). The section also allows for virtual marking.

News-At-A-Glance

STRIKE FORCE INDICTMENTS: Law enforcement unsealed indictments Sept. 6 and 7 against 70 individuals as a result of Medicare Fraud Strike Force investigations in six cities that uncovered roughly $264 million in fraudulent claims, according to the Department of Justice (DOJ), Department of Health and Human Services (HHS), and HHS Office of Inspector General (OIG). The indictments by the strike forces, which are joint HHS-DOJ teams composed of federal, state, and local law enforcement operatives, were in Miami; Houston; Baton Rouge, La.; Los Angeles; Brooklyn, N.Y.; and Chicago. The 70 indictments were coordinated with strike force enforcement activity from the past two weeks, when charges of Medicare fraud were brought in Detroit, Miami, and Dallas, totaling $31 million in false claims. In Miami, charges were filed against 45 individuals for participating in Medicare fraud schemes that totaled $160 million in fraudulent claims. In Houston, charges were filed against two individuals for participating in Medicare fraud schemes that totaled $62 million in false claims.

MACS TO ISSUE DEMAND LETTERS: Provider demand letters for overpayments identified by Recovery Audit Contractors (RACs), currently issued by the RACs, will be issued by Medicare Administrative Contractors (MACs) effective Jan. 1, 2012, according to a July 29 transmittal from the Centers for Medicare and Medicaid Services (CMS). The transmittal said that the switch would increase the consistency and efficiency of the RAC program by reducing delays in the production of demand letters. According to the CMS transmittal, once a RAC identifies an overpayment, it will submit a claims adjustment to the appropriate MAC, which then will issue an automated demand letter. The MAC will be responsible for handling all administrative correspondence related to the demand letter, including the time frame for repayment as well as the provider appeals process, while the RACs will only be responsible for correspondence directly related to their audit, such as the rationale behind the identification of an overpayment.

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