

Smart Grid standards, priorities, and gaps, on the overall direction, status, and health of the Smart Grid implementation by the Smart Grid industry, and on Smart Grid Interoperability Panel activities, including the direction of research and standards activities. Background information on the Committee is available at <http://www.nist.gov/smartgrid/committee.cfm>.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the Smart Grid Advisory Committee (SGAC or Committee) will meet in open session on Tuesday, December 18, 2012 from 8:30 a.m. to 5:00 p.m. Eastern time and Wednesday, December 19, 2012 from 8:30 a.m. to 12:00 p.m. Eastern time. The meeting will be open to the public and held in Lecture Room A, in the Administration Building at NIST in Gaithersburg, Maryland. The primary purposes of this meeting are to discuss NIST's response to recommendations from the Committee's report and to receive presentations on cybersecurity coordination and the NIST Smart Grid Program Plan. The agenda may change to accommodate Committee business. The final agenda will be posted on the Smart Grid Web site at <http://www.nist.gov/smartgrid>.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's affairs are invited to request a place on the agenda by submitting their request to Cuong Nguyen at cuong.nguyen@nist.gov or (301) 975-2254 no later than 5:00 p.m. Eastern time, Tuesday, December 11, 2012. On Tuesday, December 18, 2012, approximately one-half hour will be reserved at the end of the meeting for public comments, and speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be about 3 minutes each. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements to the Office of the National Coordinator for Smart Grid Interoperability, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8200, Gaithersburg, MD 20899-8200; fax 301-975-4091; or via email at nistsgfac@nist.gov.

All visitors to the NIST site are required to pre-register to be admitted.

Anyone wishing to attend this meeting must register by 5:00 p.m. Eastern time, Tuesday, December 11, 2012, in order to attend. Please submit your full name, time of arrival, email address, and phone number to Cuong Nguyen. Non-U.S. citizens must also submit their country of citizenship, title, employer/sponsor, and address. Mr. Nguyen's email address is cuong.nguyen@nist.gov and his phone number is (301) 975-2254.

Dated: November 20, 2012.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2012-28876 Filed 11-28-12; 8:45 am]

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DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. PTO-C-2012-0049]

Notice of Public Roundtable on Genetic Diagnostic Testing

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of public roundtable.

SUMMARY: The United States Patent and Trademark Office ("USPTO") is interested in gathering additional information on independent second opinion genetic diagnostic testing for purposes of preparing a report on the subject as required by the America Invents Act ("AIA" or "Act"). To assist in gathering this information, the USPTO invites the public to attend a roundtable focused on genetic diagnostic testing.

Public Roundtable: The USPTO will hold a public roundtable in support of the genetic testing study. The roundtable will be held on Thursday, January 10, 2013, beginning at 1:00 p.m. Eastern Standard Time (EST) and ending at 4:00 p.m. (EST) in Alexandria, Virginia.

Those wishing to share commentary at the roundtable must request an opportunity to do so in writing no later than December 20, 2012. The request must include the following: (1) The name of the person wishing to share commentary; (2) the person's contact information (telephone number and email address); (3) the organization(s) the person represents, if any; and (4) an indication of the amount of time requested for the commentary. Requests to share commentary must be submitted by email to Saurabh Vishnubhakat at saurabh.vishnubhakat@uspto.gov. Based upon the requests received, an

agenda will be sent to all requesters and posted on the USPTO Internet Web site (address: www.uspto.gov/americaninventsact).

Speakers sharing commentary at the roundtable must submit a document explaining their position for inclusion in the record of the proceedings no later than thirty days after the roundtable. Written commentary should not exceed 25 pages using at least 12-point and double-spaced font. Because written commentary will be made available for public inspection, information that a speaker does not desire to be made public, such as a telephone number, should not be included in the written comments.

The public roundtable will be available via Web cast. Information about how to access the Web cast will be posted on the USPTO's Internet Web site (address: <http://www.uspto.gov/americaninventsact>) before the public roundtable.

A transcript of the roundtable will be available on the USPTO Internet Web site (address: www.uspto.gov/americaninventsact) shortly after the roundtable.

ADDRESSES: The public roundtable will be held at the USPTO in the Madison Auditorium on the concourse level of the Madison Building, located at 600 Dulany Street, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Saurabh Vishnubhakat, Expert Advisor, Office of Chief Economist, by telephone at 571-272-9300, or by email at saurabh.vishnubhakat@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 27 of the AIA charges the Director of the USPTO with delivering to Congress a study and recommendations no later than nine months after the enactment of the Act (i.e., by June 15, 2012) regarding independent second opinion genetic diagnostic testing where patents and exclusive licenses exist that cover primary genetic diagnostic tests. Congress has mandated that the study include an examination of at least the following:

(1) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses;

(2) The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test;

(3) The impact that current exclusive licensing and patents on genetic testing

activity has on the practice of medicine, including but not limited to the interpretation of testing results and performance of testing procedures; and

(4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

In the Act, Congress defined the term “confirming genetic diagnostic test activity” to mean the performance of a genetic diagnostic test, by a genetic diagnostic test provider, on an individual solely for the purpose of providing the individual with an independent confirmation of results obtained from another test provider’s prior performance of the test on the individual.

Recognizing the diversity and complexity of the public policy issues surrounding independent second opinion genetic diagnostic testing, the USPTO conducted a thorough review of the academic and scientific literature, took notice of several published reports, and actively sought diverse and sophisticated input from the public. In that last regard, the Office published a notice in the **Federal Register** and on the USPTO public Web site dedicated to AIA implementation (AIA micro-site), seeking written comments and announcing two public hearings for this study. See *Request for Comments and Notice of Public Hearings on Genetic Diagnostic Testing*, 77 FR 3748 (Jan. 25, 2012). The Office also provided the public with a dedicated email address and a contact person in the USPTO to receive comments.

As announced in the **Federal Register** and on the AIA micro-site, the Office held two public hearings dedicated to taking public comment for this report. The first occurred at the USPTO headquarters in Alexandria, Virginia, on Thursday, February 16, 2012, and the second took place at the University of San Diego School of Law in San Diego, California, on Friday, March 9, 2012. At the hearings, witnesses provided pre-scheduled testimony, and members of the audience provided spontaneous testimony. Representatives from the USPTO attended the hearings and actively questioned all witnesses. Also, witnesses exchanged comments with the audience.

In the final days before the deadline for receipt of written comments, the Supreme Court of the United States issued two rulings with potential ramifications for the present study. The first was a memorandum opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). The second was an order in *Association for Molecular Pathology v. Myriad Genetics*, 132 S. Ct. 1794

(2012), granting the petition for a writ of certiorari, vacating the decision of the United States Court of Appeals for the Federal Circuit (CAFC), and remanding the case for reconsideration in light of the *Mayo* decision. Accordingly, the USPTO published a notice on the AIA micro-site seeking additional public input, within ten calendar days, regarding the impact of the Supreme Court’s actions on independent second opinion genetic diagnostic testing.

Through the **Federal Register** notice and hearings, the Office received twenty-seven sets of written comments and testimony from eighteen witnesses. Respondents with written comments, many of whom also testified, included four U.S. intellectual property organizations, thirteen U.S. companies and organizations, three U.S. patent practitioners, and seven members of the public speaking as individuals.

On August 28, 2012, the Department of Commerce sent a letter to the House and Senate Judiciary Committee leadership updating them on the status of the genetic testing report. The letter stated in part: “Given the complexity and diversity of the opinions, comments, and suggestions provided by interested parties, and the important policy considerations involved, we believe that further review, discussion, and analysis are required before a final report can be submitted to Congress.” After this additional public roundtable, the USPTO will follow next steps and fulfill its obligation to Congress.

Issues for Comment: The USPTO seeks comments on how to address the issue of independent second opinion genetic diagnostic testing and its relationship to medical care and medical practice, the rights of innovators, and considerations relevant to medical costs and insurance coverage. The issues enumerated below are as posed in the AIA and serve as a preliminary guide to aid the USPTO in collecting further relevant information and to evaluate possible administrative or legislative recommendations that may be provided to Congress. The tenor of the following issues should not be taken as an indication that the USPTO has taken a position or is predisposed to any particular views. The public is invited to address any or all of these issues. The public also is invited to provide input on other issues believed to be relevant to the scope of the study in addition to those listed below.

(1) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing,

and on inhibiting innovation to existing testing and diagnoses;

(2) The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test;

(3) The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to the interpretation of testing results and performance of testing procedures; and

(4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

Dated: November 21, 2012.

David J. Kappos,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2012–28890 Filed 11–28–12; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2012–HA–0142]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the Office of the Assistant Secretary of Defense for Health Affairs announces the proposed extension of a public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 28, 2013.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods: