DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO–P–2012–0003]

Request for Comments and Notice of Public Hearings on Genetic Diagnostic Testing

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Request for comments; notice of public hearings.

SUMMARY: The United States Patent and Trademark Office (''USPTO'') is interested in gathering information on the 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 provide comments and to attend public hearings addressing genetic diagnostic testing.

Public Hearings: The USPTO will hold two public hearings in support of the genetic testing study. The first public hearing will be held on Thursday, February 16, 2012, beginning at 9 a.m., Eastern Standard Time (EST), and ending at 4 p.m., EST, in Alexandria, Virginia. The second public hearing will be held on Friday, March 9, 2012, beginning at 9 a.m., Pacific Standard Time (PST), and ending at 4 p.m., PST, in San Diego, California.

Those wishing to present oral testimony at either hearing must request an opportunity to do so in writing no later than February 8, 2012. Requests to testify should indicate the following: (1) The name of the person wishing to testify; (2) the person's contact information (telephone number and email address); (3) the organization(s) the person represents, if any; (4) an indication of the amount of time needed for the testimony; and (5) a preliminary written copy of the testimony. The USPTO asks for a preliminary written copy of the testimony in order to better prepare for pre-scheduled witness testimony. Requests to testify must be submitted by email to Saurabh Vishnubhakat at *saurabh.vishnubhakat@uspto.gov*. Based upon the requests received, an agenda for witness testimony will be sent to testifying requesters and posted on the USPTO Internet Web site (address: *www.uspto.gov/americainventsact*).

Speakers providing testimony at the hearings should submit a written copy of their testimony for inclusion in the record of the proceedings no later than March 26, 2012.

The public hearings will be available via Web cast. Information about the Web cast will be posted on the USPTO's Internet Web site (address: *http://www.uspto.gov/americainventsact*) before the public hearing.

Transcripts of the hearings will be available on the USPTO Internet Web site (address: *www.uspto.gov/americainventsact*) shortly after the hearings.

Written Comments: Written comments should be sent by email to *genetest@uspto.gov*. Comments may also be submitted by postal mail addressed to Saurabh Vishnubhakat, Attorney Advisor, Office of Chief Economist, United States Patent and Trademark Office, Mail Stop External Affairs, P.O. Box 1450, Alexandria, VA 22313–1450. Although comments may be submitted by postal mail, the USPTO prefers to receive comments via email. The deadline for receipt of written comments is March 26, 2012. Written comments should be identified in the subject line of the email or postal mailing as ''Genetic Testing Study.''

Because written comments and testimony will be made available for public inspection, information that a respondent does not desire to be made public, such as a phone number, should not be included in the testimony or written comments.

ADDRESSES: The first public hearing 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.

The second public hearing will be held at the Joan B. Kroc Institute for Peace & Justice, University of San Diego, 5998 Alcalá Park, San Diego, California 92110.

FOR FURTHER INFORMATION CONTACT: Saurabh Vishnubhakat, Attorney 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 shall 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.

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 questions enumerated below are a preliminary guide to aid the USPTO in collecting relevant information and to evaluate possible administrative or legislative recommendations that may be provided to Congress. The tenor of the following questions 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 answer any or all of these questions. The public is also invited to submit comments on other issues that they believe are relevant to the scope of the study in addition to those listed below.

(1) Currently, how widely available are primary genetic diagnostic tests? How often are such tests prescribed? What are the limitations, if any, on the availability of primary genetic diagnostic tests? If there are limitations on such availability, what are the consequences in terms of the quality of care, human health and medical costs of such limitations? How has the practice of medicine, the quality of care that patients receive, and medical costs and insurance coverage been affected, if at all, by the availability of primary genetic diagnostic tests?

(2) What is the amount and scope of patenting in the field of genetic diagnostic testing? What role, if any, does patenting play in the availability of primary genetic diagnostic testing?

(3) With respect to primary genetic diagnostic tests, how widely available are independent second opinion genetic diagnostic tests? What are the various organizational methods used to make such independent second opinion genetic diagnostic tests available?

(a) What are the limitations, if any, on the availability of such independent second opinion diagnostic tests?

(b) Are any such limitations organizational, associated with the level of quality or demand, or driven by other internal or external factors?

(4) What impact does the availability of independent second opinion genetic diagnostic tests have on the level of care that physicians are able to provide?

(a) Does the current level of availability of independent second opinion genetic diagnostic tests affect the medical decisions and judgment of physicians?

(b) Does the current level of availability of independent second opinion genetic diagnostic tests affect the quality of care received by patients?

(c) Does the current level of availability of independent second opinion genetic diagnostic tests affect the reliability of information presented to patients?

(d) Are there practical consequences of the current availability of independent second opinion genetic diagnostic tests, in terms of patient health, quality of life, and longevity? In terms of the practice of medical care? Are these consequences, if any, relatively rare, or common and widespread?

(5) Is the availability of independent second opinion genetic diagnostic tests related in any manner to innovation in the health care field, especially as relates to the introduction of new or improved techniques associated with existing genetic tests and diagnostic methods?

(6) To the extent that independent second opinion genetic diagnostic tests are not available, what are the appropriate methods for making them more widely provided?

(a) What entities or institutions, if any, should play an active role in ensuring that independent second opinion genetic diagnostic tests are more widely provided? What is the basis for your recommendation in terms of providing the maximum benefit at the appropriate level of cost?

(b) What entities or institutions, if any, should not play a role in ensuring that independent second opinion genetic diagnostic tests are more widely provided?

(7) What public policies, if any, should the Federal Government explore in order to ensure that independent second opinion genetic diagnostic tests are more widely provided? Is the widespread availability of such tests the only issue the Federal Government should consider in fashioning such public policies? Are there public policies that the Federal Government should not explore?

(8) What effect would providing more widespread access to independent second opinion genetic diagnostic tests have on existing owners and license holders of patents that cover genetic diagnostic tests? How should policy makers consider the relationship of patents, which may cover purified genetic substances, to proprietary data derived from conducting tests, each of which may be useful in both improving high quality and wide access to testing but may also provide important competitive advantages that can drive investments in research and development?

(9) What effects, if any, do patents and exclusive licenses have on genetic diagnostic testing?

(a) What effects, if any, do patents and exclusive licenses on genetic diagnostic tests have upon the development of new testing procedures?

(b) What effects, if any, do patents and exclusive licenses on genetic diagnostic tests have upon how new testing procedures are performed?

(c) What effects, if any, do patents and exclusive licenses on genetic diagnostic tests have upon the interpretation of testing results?

(d) What effects, if any, do patents and exclusive licenses on genetic diagnostic tests have upon the further improvement of testing procedures?

(10) What are the pecuniary costs associated with genetic diagnostic testing?

(a) Are there substantial differences between the pecuniary costs of patented genetic diagnostic tests and unpatented genetic diagnostic tests? To the extent that there are cost differences, are these differences attributable to the patents themselves, or are there other factors that may be driving the differences?

(b) Are there substantial differences between the pecuniary costs of patented genetic diagnostic tests and unpatented genetic diagnostic tests available for the same medical disorder? To the extent that there are cost differences, are these differences attributable to the patents themselves, or are there other factors that may be driving the differences?

(11) What effect does pecuniary cost have on patient access to genetic diagnostic tests?

(a) What effect does the cost of primary genetic diagnostic testing have on the likelihood that patients will request such tests? What effect does the cost of an independent second opinion genetic diagnostic testing have on the likelihood that patients will request such tests?

(b) What effect does the cost of primary genetic diagnostic testing have on the likelihood that physicians will prescribe such tests? What effect does the cost of independent second opinion genetic diagnostic testing have on the likelihood that physicians will prescribe such tests?

(12) How extensive is medical insurance coverage for genetic diagnostic testing? What are the differences, if any, between the level of insurance coverage available for genetic diagnostic tests covered by patents and the level of insurance coverage of unpatented genetic diagnostic tests for the same diseases or disorders?

(13) What effect does insurance coverage have on patient access to genetic diagnostic tests?

(a) What effect does the insurance coverage of genetic diagnostic testing have on the likelihood that patients will request such tests? What effect does the insurance coverage of independent second-opinion genetic diagnostic testing have on the likelihood that patients will request such tests?

(b) What effect does the insurance coverage of genetic diagnostic testing have on the likelihood that physicians will prescribe such tests? What effect does the insurance coverage of independent second-opinion genetic diagnostic testing have on the likelihood that physicians will prescribe such tests?

(14) What effect do patents and exclusive licenses have on the availability of insurance coverage for genetic diagnostic tests?

(a) To what extent, if at all, do insurance companies currently cover the costs of independent second opinion genetic diagnostic tests?

(b) Can you provide evidence that any price differential in the cost of such tests is attributable to patents and exclusive licenses, and that any such price differential is a substantial barrier to insurance coverage of independent second opinion genetic diagnostic tests?

Dated: January 18, 2012.

David J. Kappos,

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

[FR Doc. 2012–1481 Filed 1–24–12; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Department of the Air Force

U.S. Air Force Academy Board of Visitors Notice of Meeting

AGENCY: U.S. Air Force Academy Board of Visitors.

ACTION: Meeting notice.

SUMMARY: In accordance with 10 U.S.C. 9355, the United States Air Force Academy (USAFA) Board of Visitors (BoV) will hold a meeting in Harmon Hall at the United States Air Force Academy in Colorado Springs, Colorado on 10–11 Feb 2012. The meeting sessions on 10 Feb will begin at 4 p.m. and the meeting sessions on 11 Feb will begin at 8 a.m. The purpose of this meeting is to review morale and discipline, social climate, curriculum, instruction, infrastructure, fiscal affairs, academic methods, and other matters relating to the Academy. Specific topics for this meeting include a Faculty Focus Group; Religious Training and Respect; the Superintendent and Command Chief Update; Diversity in the Athletic Department; the Air Force Academy Athletic Corporation Transition Plan Update; Character Update; Focus Group (Gold Bar Lieutenants on Diversity Recruiting); Center for Character and Leadership Development Military Construction Update; and the Personnel Update. In accordance with 5 U.S.C. 552b, as amended, and 41 CFR 102–3.155, the Administrative Assistant to the Secretary of the Air Force, in consultation with the Office of the Air Force General Counsel, has determined in writing that the public interest requires two sessions of this meeting shall be closed to the public because they will involve matters covered by subsection (c)(6) of 5 U.S.C. 552b.

Public attendance at the open portions of this USAFA BoV meeting shall be accommodated on a first-come, first-served basis up to the reasonable and safe capacity of the meeting room. In addition, any member of the public wishing to provide input to the USAFA BoV should submit a written statement in accordance with 41 CFR 102–3.140(c) and section 10(a)(3) of the Federal Advisory Committee Act and the procedures described in this paragraph. Written statements must address the following details: The issue, discussion, and a recommended course of action. Supporting documentation may also be included as needed to establish the appropriate historical context and provide any necessary background information. Written statements can be submitted to the Designated Federal Officer (DFO) at the Air Force address detailed below at any time. However, if a written statement is not received at least 10 calendar days before the first day of the meeting which is the subject of this notice, then it may not be provided to, or considered by, the BoV until its next open meeting. The DFO will review all timely submissions with the BoV Chairperson and ensure they are provided to members of the BoV before the meeting that is the subject of this notice. For the benefit of the public, rosters that list the names of BoV members and any releasable materials presented during the open portions of this BoV meeting shall be made available upon request.

If, after review of timely submitted written comments, the BoV Chairperson and DFO deem appropriate, they may choose to invite the submitter of the written comments to orally present the issue during an open portion of the BoV meeting that is the subject of this notice. Members of the BoV may also petition the Chairperson to allow specific personnel to make oral presentations before the BoV. In accordance with 41 CFR 102–3.140(d), any oral presentations before the BoV shall be in accordance with agency guidelines provided pursuant to a written invitation and this paragraph. Direct questioning of BoV members or meeting participants by the public is not permitted except with the approval of the DFO and Chairperson.

FOR FURTHER INFORMATION CONTACT: For additional information or to attend this BoV meeting, contact Capt Bobby Hale, Chief of Holm Center Programs, Commissioning Programs Division, AF/A1DO, 1500 Perimeter Road, Suite 4750, Joint Base Andrews, MD 20762–6604, (240) 612–6252.

Bao-Anh Trinh,

Air Force Federal Register Liaison Officer.

[FR Doc. 2012–1357 Filed 1–24–12; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant a Partially Exclusive License; Cobalt Technologies, Inc.

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to Cobalt Technologies, Inc., a revocable, nonassignable, partially exclusive license in the United States to practice the Government-owned inventions described in the following: patent application 61/562231: Water and Contaminants Removal From Butanol Fermentation Solutions and/or Broths Using a Brine Solution, filed on November 21, 2011.//patent application 61/527943: Dehydration of Bio-Derived Alcohols to Alkenes Using Highly Selective Catalysts, filed on August 26, 2011.//patent application 12/511796: Diesel and Jet Fuels Based on the Oligomerization of 1-Butene, filed on July 29, 2009.//patent application 12/769757: Turbine and Diesel Fuels and Methods of Making the Same, filed on April 29, 2010.//patent application 13/095245: Selective Isomerization and Oligomerization of Olefin Feedstocks for the Production of Turbine and Diesel Fuels, filed on April 27, 2011.//patent application 13/095290: Selective Isomerization and Oligomerization of Olefin Feedstocks for the Production of Turbine and Diesel Fuels, filed on April 27, 2011.//patent application 13/095201: Selective Isomerization and Oligomerization of Olefin Feedstocks for the Production of Turbine and Diesel Fuels, filed on April 27, 2011.//patent application 61/585943: New Homogeneous Metallocene Ziegler-Natta Catalysts for the Oligomerization of Olefins in Aliphatic-Hydrocarbon Solvents, filed on January 12, 2012.

DATES: Anyone wishing to object to the grant of this license must file written objections along with supporting evidence, if any, not later than February 9, 2012.

ADDRESSES: Written objections are to be filed with the Office of Research and Technology Applications, Naval Air Warfare Center Weapons Division, Code 4L4000D, 1900 N. Knox Road Stop 6312, China Lake, CA 93555–6106.

FOR FURTHER INFORMATION CONTACT: Michael D. Seltzer, Ph.D., Office of Research and Technology Applications, Naval Air Warfare Center Weapons Division, Code 4L4000D, 1900 N. Knox Road Stop 6312, China Lake, CA 93555–